EXHIBIT 2H

WAVE 1

EXHIBIT

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC, REPAIR SYSTEM PRODUCTS, LIABILITY LITIGATION	) MASTER FILE NO. 2:12-MD-02327) MDL NO. 2327) JOSEPH R. GOODWIN) US DISTRICT JUDGE
THIS DOCUMENT RELATES TO CAROLYN LEWIS, ET AL. V. ETHICON, INC. CASE NO. 2:12-CV-04301	))))

THURSDAY, NOVEMBER 14, 2013

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Deposition of Prof. Dr. Med. Uwe Klinge, Volume I, held at the Quellenhoff Hotel, Monheimsallee 52, 52062 Aachen, Germany, commencing at 9:01 a.m., on the above date, before Carrie A. Campbell, Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter, and Certified Court Reporter.

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EXHIBITS

(Exhibits attached to the deposition.)

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– – –

PROF. DR. MED. UWE KLINGE, of lawful age, having been first duly sworn to tell the truth, the whole truth and nothing but the truth, deposes and says on behalf of the Defendants, as follows:

DIRECT EXAMINATION

QUESTIONS BY MR. THOMAS:

Q. Good morning, Doctor.

A. Good morning.

Q. It has been just a little bit more than a year since we saw each other.

A. Yeah. Yeah.

Q. What have you been --

A. My daughter is much heavier.

Q. Taller you mean?

A. Taller and heavy. Very heavy.

Q. How old is your daughter now?

A. How old? She's going to be one and a half year.

Q. Oh, wonderful.

Since we saw each other last, I know that you've testified in the Gross trial, correct, in New Jersey?

A. Yes.

Q. What else have you done with your professional time in the last year?

A. Professional time, do you mean what I -- what I'm -- what I was working on?

Q. Yeah, let me ask you a little more specifically. That's probably too general.

You've continued to work at the university?

A. Yes.

Q. You've continued in the same position at the university?

A. Yes.

Q. Have you taught any classes at the university in the last year?

A. Yes.

Q. What classes have you taught in the last year?

A. I am included in the classes for -- to have lessons for the students in -- that are learning surgery. That is the third year of the students in their curriculum, and there's another class that all of the

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students learning medicine for dentists. They also have to pass some lessons from surgeons and there I'm included.

Q. Okay. Any other classes that you've been involved in since October of last year?

A. Not at the university, no.

Q. Have you made any presentations in the last year?

A. Yes.

Q. How many?

A. Maybe ten. Publications at conferences.

Q. Right. That's what I'm talking about.

A. Yeah.

Q. And who are the sponsors of these conferences?

A. Usually it has been invitations by the organizers of the Berlin hernia conference, of the European Hernia Society, of the German Hernia Society and some others. Usually there are five, six companies acting as sponsors for these ones, and usually they

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have a company that are organizing the invitations, the travel expenses and so.

So it is going directly to these companies. Not to a specific sponsor that is most of these.

Q. When you talk about companies, are you talking about medical device manufacturers?

A. It's usually medical device. It's Covidien, it's Ethicon. Ethicon is usually the gold sponsor, but it is Covidien, Brown in Germany, DynaMesh® is some sponsor there.

So you always find it at the documents of the conferences which -- the list of the main sponsors for the European Hernia Society, I think for this meeting in Duns, the list is longer than for some local meetings.

Q. When you say DynaMesh®, you're referring to the company FEG?

A. Yes, it is. There is some relation.

Q. I thought FEG made DynaMesh®?

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A. Yes.

Q. Okay. When you said "there's some relation," are they -- is there something I'm missing?

A. As far as I know and we already discussed it, DynaMesh® is the brand name of the product, and here we have a company and this is the FEG. When it started it. Whether the DynaMesh® meanwhile has its own company, I don't know.

Q. That's fine. That's what I understood.

A. So, therefore, this is this mixing up of these terms.

Q. Okay. I didn't want to mix it up. I just thought I may have missed something. I'm just trying to understand.

Now, when you've attended these conferences, are you paid to attend?

A. No. No. Never.

Q. Are your expenses reimbursed?

A. Usually. As I'm an invited speaker, they always took the costs of the hotel and the flight or train or car.

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Q. Do you receive an honorarium for presenting?

A. No, never.

Q. Do you receive -- strike that.

Have you attended -- strike that again.

Have you spoken at any conferences sponsored solely by FEG?

A. Yes. There is a -- yes.

Q. How many times in the last year?

A. It is -- I remember three times.

Q. And where have you spoken at conferences sponsored by FEG in the last year?

A. There has been a master class that is organized by Professor Berger in Baden-Baden. He's the head of the German Hernia Society and -- no, excuse me, I have to correct. Last year it was stopped because they have -- they are under reconstruction. It has been planned, but last year we didn't do it, but we will do it next week.

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Q. Okay.
A. And the year before.
Q. All right.
A. So, therefore, I have to put that out.
Q. And what is that conference that happened two years ago --
A. This master class?
Q. Yes.
A. About 20, 20 to 30 international surgeons, about 30 international surgeons are coming there together and they are -- they want to see how Professor Berger, who is one of the famous surgeons who is doing laparoscopic incisional hernia repair and parastomal hernia, he's a real expert there and they want to see how he operates it, and this occasion we are discussing problems in this field with the participants, and I'm the moderator and I'm presenting some overviews, some reviews of our past work there.
Q. Okay. So if that conference doesn't count, then you've done two

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conferences for FEG in the last year, correct?
A. As I remember, yes.
Q. Tell me what the other two are.
A. The other was a meeting at Cologne at the University of Cologne where Professor Jager presented his innovative procedure to treat incontinence. And I was part as Dr. Klosterhalfen to present some basics, some science there at that conference.
Q. And this was the conference organized by Professor Shaffer?
A. It was Yaeger. Yaeger. His name is Professor Yaeger. You will find it in the internet. He has an excellent web page where he presented his new procedure, how he addresses -- how he treats it.
Q. And --
A. By laparotomy through the abdomen he placed an implant there.
Q. And that was for the treatment of stress urinary incontinence?
A. Urgent stress.

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Q. And what kind of implant did he recommend to be used?
A. He has been working or he worked on this for, I think, for the past five to ten years and he originally tried it with ePTFE, but he has some -- several problems and finally he found the FEG, the small medium enterprises, and they constructed during the past two, three years this device. This device is a combination of a sling-like, it has sling-like parts, and it has flat mesh-like parts for the fixation of the vagina.
So it's a combination with different parts in the device which each of them is specifically designed to the local function in this one. It's complex.
Q. What kind of polymer is used?
A. PVDF.
Q. Did you know of this innovative procedure prior to attending the conference?
A. Yes. I've seen the internet, I've seen the document which is there about this procedure and I've seen the device.

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Q. Have you worked with Dr. Yaeger in the development of the device?
A. In some regards. So I'm not specifically asked whether it should be three or four filaments in a specific area because this is a decision by the surgeon, by Professor Yaeger. But once upon a time, I'm asked whether this construction fits to what we have learned. What is our experience for the behavior of textiles in tissues that we have learned during the past 20 years. So I had to check whether it -- there may be some problems or not and, therefore, I had to look to this.
Q. Had you worked with Dr. Yaeger in the past?
A. Professor Yaeger?
Q. Yes.
A. I only met him there, and later on I met him in Barcelona where we had another meeting together.
Q. How did you happen to work with Professor Yaeger on this innovative procedure?

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MR. ANDERSON: Other than what he's already mentioned?
QUESTIONS BY MR. THOMAS:
Q. How did you two come together is what I want to know.
A. I was -- I was asked by the FEG, they told me that they have a new concept. They have a new idea that they are going to work on this and if they are -- if I'm able to have a look to this.
Q. Okay. And who --
A. This is --
Q. I am sorry.
MR. ANDERSON: Are you through? Go ahead.
THE WITNESS: No. It's --
QUESTIONS BY MR. THOMAS:
Q. Who at FEG asked you to speak with Professor Yaeger about this new device that used PVDF?
A. It is either Boris Obolensky or Dr. Andreas Mullen.
Q. And did you meet with Professor Yaeger to discuss this device?

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A. I met him first time in Cologne at this conference.
Q. Okay. How did you consult with Professor Yaeger on this new device?
A. I didn't get --
Q. I am sorry, let me ask the question this way.
You told me a minute ago, I think, that you were asked by FEG to look at the proposed device and give your opinions about -- based upon the work that you've done for the past 20 years to determine whether this device is consistent with what you've found.
Is that correct?
A. Yes.
Q. Is that work that you did at the request of FEG?
A. They gave me the questions to this device and I answered to them. Because it's usually a matter of textile properties, textile characteristic, pores and so on and, therefore, it was a conversation with the engineers from the FEG.

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Q. I see.
And so the work that you did on this device was not working with Professor Yaeger, is that fair?
A. That is fair. Yeah, that is.
Q. So all of the work that you did on the device was in consultation with the engineers at FEG?
A. Yes. Or maybe sometimes there has been a feedback loop. They're talking to Professor Yaeger and then so there is another question.
Q. How much time --
A. It's not so strict that there is one question, one answer and so --
Q. How much time did you spend consulting with FEG on the development of this new device?
A. It is very difficult to answer this question because when they -- when I got a question to this and I have to answer it, I have to summarize all of my experience and all my knowledge to this one. Maybe sometimes the answer was in two minutes, but

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it wouldn't be fair to say that I'm working just two minutes for this.
Q. Well, did you --
A. Because all --
Q. Go ahead.
A. Yeah.
Q. Did you keep track of the time that you spent working on this project with FEG?
A. No.
Q. Did you charge FEG for the time that you spent working on this project?
A. Not specifically for this project, but I am consulting for them. I'm helping them in medical questions. They are mainly engineers without a medical profession and, therefore, for many medical questions, they like to ask me and for this time effort, I got a compensation.
Q. And how are you compensated by FEG?
A. I got about 25,000 -- no, 30,000 Euros a year, once a year.
Q. Do you have a contract with

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FEG?
A. There is as I -- so far I remember, I do not have a contract where I agreed or where I said that I will work for something for several hours for this amount of money. I don't have such a contract. There is no contract.
I know that there has been or I've signed a contract that we work together. It was in relationship to a patent, the FEG claim for it, and they placed my name as well as Klosterhalfen as well as others who contribute to this patent on PVDF meshes, and in this relation, I have signed that I have been or that I'm working with the FEG together. It's a general contract without any specific agreements how to work, where to work.
Q. Are you paid by the FEG based on the amount of mesh that FEG sells?
A. Definitely not.
Q. How is your compensation calculated?
A. They -- so far I know, they

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calculated if they are -- if they had a good year, they said, okay, I -- they want me to participate at a good year. So sometimes it was 20,000 Euros a year, meanwhile it is 30,000 Euros a year, but it is an overall estimate by them.
Q. So the better the company does, the more money you make, is that fair?
A. I don't know, but overall, yeah, maybe. But I have no obligation to do anything or I have no expectation that it happens next year. So it's just an expression of how we have been working together, and it is a cheaper solution for them to ask me as a consultant than to employ a medical doctor and they will never get someone with my expertise on the market. So I think it's a good agreement for both of us.
Q. And do you have a written agreement with the FEG that you look to to determine your -- the duties and obligations of both parties? Is there a written contract?
A. No. No. As I told you, it's

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just once a year they coming up and said, "Okay, the last year, you did a lot and we're able to give you a compensation for this spare time that you invested and, therefore, we would be happy to give this to you."
Q. Okay.
A. And that is the reason maybe that we continue this work. Otherwise, we would have to think about it. But there is no written contract that I have to do it for the next year or that they expect me something. No, it's free.
Q. Do you have a written contract of any kind with FEG?
A. Apart from this general statement in relation -- in relation to these patent affair, it was six, seven years ago, but I cannot really remember the details for this. But I usually refused to have this strict contract as I had it with Ethicon. I never had it with the FEG like this.
Q. To your knowledge and recollection, does the contract that you have that relates to the patents provide that you

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receive compensation for the sale of products?
A. So far I know from the German law, there is an obligation of someone who has a patent to share the royalties with those guys that are -- have been working on the patents. But so far I'm informed is that the law does not define the amount. It can be very small. It depends of the medical device.
Q. Okay.
A. So I do not recollect any figure that it is .5, 2 or 3 percent or so.
Q. Have you received royalties from the FEG for the sale of any of their products?
A. As a consequence of the not existing contract there and I refuse to have this contract, as I told you several times, I never got what you may call royalties.
Q. That's my question.
A. Yes.
Q. Did you receive royalties --
A. Never.

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Q. Let me finish my question, please.
A. Sorry.
Q. Did you receive royalties in addition to this arrangement that we've already discussed where you've received 20 to 30,000 Euros a year?
A. Definitely not.
Q. Okay. Do you have an agreement with the FEG that the 20 to 30,000 Euros that you've received is in place of any royalties that you might receive under that patent agreement?
A. No.
Q. Okay.
A. It is a compensation for the time I spent the last year.
Q. You talked about the meeting in Cologne.
What was the other meeting in the last year where you attended where it was sponsored by FEG?
A. The last meeting has been just recently in Barcelona where we had a meeting

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that has been organized by the -- or that has been sponsored by the FEG in Barcelona at the occasion of the international society -- incontinence society of this meeting in Barcelona there, and there was a scientific presentation there that includes the requirements to the function presented by Dr. Liedl from Munich. It was Professor Yaeger who presented his way to overcome this anatomical dysfunction in these patients, and it was planned to have an overview what can be done by textile engineers by Dr. Mullen, but, unfortunately, as I made a very poor time management, it has to be stopped. He was not able to make his presentations there.
And my function there was to give an overview from our experience of surgical meshes, which is ten years longer than for the gynecologists, and my task was to moderate between the gynecologists and the urologists because they're -- I don't know whether it's in the US as well, but in Europe, there is some competition between these two. The woman belongs to whom, they

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always complain and, therefore, me as a surgeon, I'm a little bit outside and, therefore, my task was to moderate.
Professor Yaeger is a gynecologist, Dr. Liedl is a urologist, so, therefore, I -- yeah. I helped to organize this meeting and this was this session there.
Q. How many people attended that meeting?
A. 40.
Q. 40?
A. Yeah.
Q. And it was presented to urologists and urogynecologists?
A. Yes.
Q. Was the purpose of the meeting to introduce Dr. Yaeger's new method for the treatment of stress urinary incontinence?
A. To present his idea and to give some background information about the biomechanics of the pelvis, and so some of the participants, as I noticed afterwards, they already use this device, but they wanted to have some background information there.

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Q. Did you present on the biomechanics of the pelvis, or did someone else make that presentation?
A. Dr. Liedl did that.
Q. And Dr. Liedl is what?
A. He's a urologist. He's working in Munich. He's -- yeah. He's an expert in this.
Q. Okay. Doctor, you've made about ten presentations, you've been working on a couple of classes, you testified in the Gross case.
Have you been doing any research in the last year in specific areas?
A. That is my main topic. I am still a surgeon, once a surgeon, ever a surgeon. So this didn't -- does not change, but my main task is to do surgical research, research in biomaterials, research in hernia treatment research, in biological, morphological, cell reaction to biomaterials. That is my main thing. And in this context, I did some research projects, I prepared some manuscripts, some studies to be published.

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Q. What studies in the last year have you published or will be published?
A. Let me start from the last because it's more easy to recollect.
Submitted, we have a paper which deals with the inflammatory activity of the cells around surgical meshes and what type of cells are the major part of the foreign body granuloma of this infiltrate. We've worked some time to identify the origin of these cells there. This is one work which is submitted. There is another work I did together with some international colleagues where we had some analysis in -- general analysis the value of randomized control trials, clinical studies, in relation to the power of registries. Because this is a very important topic in particularly if you want to compare medical devices.
There is a limitation of clinical studies and that is maybe not realized fully up to now and, therefore, we -- I define some aspects there. We submitted it and we agreed. We discussed it

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at international, and then we presented it to a journal and we are waiting whether it's accepted or not.
I have another project that is working on lang -- non-small cell lung cancer and the value of biomarkers. It is -- the manuscript is in a -- it's still under work so one other colleague just -- we are waiting on his comments on it. I had -- I prepared a manuscript for the German Journal for Surgeons. They asked me to make a manuscript to the question whether you can avoid complications by selection of a mesh that is more adequate. And we made a manuscript on this topic.
There has been another request that is incisional hernia repair, whether it's necessary to make a closure of the fascia that is just finished and submitted. We had a research project where we had some knockout mice where we placed meshes, and the advantage of these genetic-transferred mice were that when the inflammatory cells are activated, they are transmitting

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luminescence. So with the camera, you can see whether there is some activation of inflammatory cells by a camera without taking the samples and killing the mice. And we compared several meshes and several coatings there and we controlled or monitored the local inflammatory response.
This was a manuscript and they want to have some additional stainings and we were just preparing them and I think we can resubmit this within the next four weeks. So this is another project.
Yeah, I'm discussing in the moment with Professor Köckerling, you know, he has a large -- the German register for hernia and in this registry, he has some information about meshes and, of course, we will talk about it in detail later on, but he wants to know the impact of meshes on the clinical results and, therefore, we started to do an analysis in respect to -- to define the impact of mesh materials that can be identified by the data of his registry.
We started to think about -- he

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started to make some analysis, and I think within the next weeks we can discuss it in detail and get some more information.
Several other -- I cannot say whether this is -- this is, of course, not complete. There are some other -- maybe you have more specific things.
Q. You've been busy.
The first one you talked about, the inflammatory activity in the cells that surround meshes; is that correct?
A. Yes.
Q. Who is on that study with you?
A. It is Professor Klosterhalfen, he's there, because, yeah. And it is Dr. Fet, F-e-t, she's the research assistant. She made this, and there is Professor Deetz from Würzburg, D-e-e-t-z. These are all of the coauthors from this.
Q. And what meshes do you analyze in that study?
A. It was -- it was part of a project that is granted by North Rhine-Westphalia and the European community,

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and one of the basic questions was to identify these cells there and we took 50 explants that has been collected at our department there.

Q. You say "our department" --

A. Surgical department going directly to our lab and having been stored there during the past five, six years.

Q. Okay.

A. And we collected these because we wanted to have a certain variation of mesh materials, a variation of procedures, a variation of complications because this was the first screening study there. Initially when we started the project, we just thought it was macrophages and nothing else and macrophages were the most important thing, so, therefore, we learned a lot during this process.

Q. So in this first study we've talked about, what you did was studied explants; is that correct?

A. Yes. Human explants.

Q. All right. What conclusions

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did your study reach?

A. The conclusion is that the inflammatory infiltrate, which you see in all these HE stainings and it is more or less thought in the last years that it is macrophages and, therefore, a lot of macrophage staining has been done there.

But now we are knowing that there are a lot of lymphocytes there, and there are cells that can be called fibrocytes. Fibrocytes has first been published by Bucala in the US ten years ago. It's a specific cell with an origin of the bone marrow and going to some site of injury and then can switch to an inflammatory macrophage or going to a fibroblast to the connective tissue production.

So this is a new cell that is maybe very, very important. The most important finding is that it is not possible to identify a specific cell just by making or by taking one biomarker. So there are a lot of cells that are positive for two, three, four, five different markers. And before

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this study, we thought that when we want to identify a cell, you take a marker, are looking if this is positive for this marker and you believe that that is a specific cell, and we have seen because we made it in parallel with 20 different markers that very many of these cells express several different markers. So it's very complex these, and we're just at the beginning. The restriction to macrophages is shortcoming.

Q. Does this study analyze the extent to which one design of a mesh may be better than another?

A. No. It is not possible because the variation -- by intention, the variation is too big.

What we can say is that there are differences. So material has an impact on the tissue response.

Q. Are you able --

A. There's no doubt about it.

Q. Are you able to conclude from the research that you've done whether PVDF or polypropylene are better meshes for the

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issues that you were studying?

A. As I told you, we're not able to make specific conclusions that one is better than the other. There is no doubt that the material has an impact and we now know that the cells are not only macrophages. We get some new ideas how to improve or how to reduce the inflammatory reaction furthermore.

So it has to be a coating not only addressing the macrophages, but a little bit other cells, stem cells or so. So we get new ideas for the general principle, but...

Q. Now, in your deposition last time, you talked a little bit about registries and I don't want to redo what we've done before.

But this study that you've worked on where you analyze the value of randomized controlled trials and clinical studies versus registries, is that a general discussion of the topic, or is it specific to a certain kind of problem like hernias?

A. I think it is, of course, it is

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an evolution of our thinking. As you surely know, I was asked by the British Journal of Surgery some years ago to make -- to make an editorial comment on the meshes, and already in this article, I mentioned that many of these questions cannot be solved by these clinical studies that we are used to, placing the one mesh in 100 other patients as well. So many of these questions cannot be solved by this.

At that time, already I -- I mentioned the problem but did not get to the solution so far, but during the following years, we had more and more discussions. We had the discussions on the occasion of the introduction of the European registries for incisional hernias in this working group as Professor Moysums.

So we have a lot of working and so finally I made this general -- this general concept to show the limitations of randomized control trials, but in this publication, there is already as a consequence that we should -- that we need

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registries as it was in others. In the manuscript for the classifications and in many other manuscripts, we already indicated that we need these data pools of registries.

Q. What problems do you think that you can address through registries that the randomized control trials and clinical studies do not adequately address?

A. To make it short, in a registry, you cannot prove the superiority of a -- and that is a sentence I think I used in this manuscript. You cannot prove the superiority of any device because you never have the absolute figures.

Q. In a registry that's true or in a trial?

A. In a registry, you cannot prove the superiority of a specific device.

Q. Okay.

A. It would be -- it would not be correct to use this data to say this device is better than the other. In a registry, it is not acceptable to do so.

The thing that you can do with

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a registry is you can detect poor performance. So if you have a device that has significantly more complications in your group than others, then you should get along by this and then you have to be very careful, you have to make further investigations to this.

So detect the inferiority phase with a registry, with a follow-up of all of these different patients, different devices, this is the only way to help you to find this. And you have a more powerful instrument to find mesh-related complications than in a clinical study with 100 patients or 200 patients. You need at least 2,000, 3,000 patients in a clinical study to have sufficient statistical power. This is the --

Q. Does this study speak specifically to mesh-related complications?

A. Not specifically, but it includes as a consequence that to address these questions because you're in the -- the incidence rate of mesh-related complications are in a percentage where you need some big

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databases, some big registries and, therefore, it is included. It is not only addressed limited to this, no.

Q. You also identified non-small cell lung cancer and the value of biomarkers.

Did I write that down right?

A. We had a study over -- it has been going over years, and at the beginning, we thought that you take some serological biomarker and you will get a good impression on the outcome of the patient, of the prognosis and then we added some histological markers. So we made in our lab stainings with some specific cell markers and then looked whether this was related to the prognosis. And we took some clinical data. So overall we got 34 -- 35 parameters, which we wanted to correlate to the prognosis.

Q. Do any of these -- strike that.

Does this study relate in any way in the study of mesh?

A. Only indirectly because it showed that these only causal relationship, you have one marker, one outcome. In

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biology, it doesn't work. It is a -- you have very much interferences, crosslinks to other things and --

Q. Does the study attempt to make an analysis of the extent to which biomarkers associated with the use of mesh are associated with non-small cell lung cancer?

A. No, definitely not.

Q. Now, the fourth one that I have on my list, the fourth study you've been working on is whether you can avoid complications by the selection of a more adequate mesh.

Is that correct?

A. It is not a study. It's -- I was asked to give a review.

Q. Okay. And what are the topics of the discussion in that review?

A. The main fields we addressed in this has been infection, it has been recurrence, it has been pain, maybe it has been adhesion, I think. Yeah, those are the topics.

Q. And -- I'm sorry.

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A. Yeah.

Q. Is that in the context of hernia repair?

A. Yes. It is the issue of this -- this issue of this journal is hernia, meshes in hernia. So it's a collection of various aspects and one -- so several authors invited to make a review to questions of hernia repair.

Q. Do you recommend a specific mesh for the use of hernia repair in this study?

A. This question is too -- so we wrote 28 pages there to address this question, and the editor just informed us that we have to shorten it by one-third so next week we have to cut it down. If you want -- if you ask me whether I recommended a specific mesh, so the question is, is there one ideal mesh, no, there isn't one ideal mesh. You have to look to the various indications, the various conditions of the patients, various problems there. But there are some -- I presented there some evidence

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that some things shouldn't be done, and if it has been done and the complication occurs, you can correct it by doing it otherwise.

Q. Is the type of material one of the things that you think you can choose in order to reduce complications in hernia surgery?

A. I don't know what you are -- what you're thinking of when you said "type of material." Of course, the characteristics of the mesh is important because I was asked what is the impact of the mesh there. It may be the polymer, it may be the textile structure, it may be the porosity, it may be, it may be.

Q. And without being too general or simple, it's the same sort of things we talked about for years and we're going to talk about later today.

Is that fair?

MR. ANDERSON: Objection.

THE WITNESS: A lot of these things we have been talking always and again and again and again, yeah.

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QUESTIONS BY MR. THOMAS:

Q. Is there anything new in this article about hernia surgery and reducing complications from hernia surgery that you haven't written before?

A. This review includes the actual reference, the actual literature, that was the intention by the editors. So you have to check whether these opinions are based on the actual literature that has been published there. And I have to say, when we said that heavy-weight is a high-risk product, it didn't change so there is still the confirmation, but now we added the recently published literature of the past two, three years.

But, yeah, they -- it was always a confirmation of what we have been working on for the past 20 years.

Q. So is it fair to say that this review article that you're working on right now is a collection of work that you've already done and others have done and is nothing new for the literature?

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A. No, that is -- that is not correct.

First of all, it is new because when we made such a review in 2005 and in 2013, you have other evidence, you have other studies that are included that are discussed there. There are -- I didn't make a review where I just copy, paste the abstract conclusion there and made it there. But you have to make a synthesis of all of these thoughts, you have to build up a structure to present it to the reader in a reasonable form and, therefore, a review is not a really study coming from the lab, but it includes a lot of intellectual work. So it is new.

Q. And you mentioned the article in 2005. Are you referring to your review article that was talked about at length in your last deposition, the review article you did with Professor Klosterhalfen on the light-weight, large pore concept of mesh construction? Is that what you're talking about?

A. Just some minutes ago I

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referred to the British Journal of Surgery.

Q. I'm sorry. Okay.

A. British Journal of Surgery, there I was invited to give a comment on the medical devices and just three, four pages and there -- yeah, therefore, the first time I outlined that we need some further studies, additional studies to understand this problem to get -- we need some other data.

Q. Okay. Is the study where you study whether -- strike that.

Is the study where you analyzed whether it's necessary to make the closure of a fascia in a certain hernia procedure, is that a pure surgical analysis? Or does that involve mesh issues?

A. I didn't get --

Q. Okay. Let me start over again. I'm reading from my notes to try to remember what you described one of these studies to be. And I think one of your studies is whether it was necessary to make a closure of the fascia in a certain hernia surgery.

A. Yes.

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Q. Is that correct?

A. Yes, that's correct. And just to explain you, this is the question that is under discussion since one, two years at surgical conferences very intensely, whether to -- it is necessary to make this fascia closure. This is a question in the field of laparoscopic hernia repair, only in this field. In open surgery, there is no question about it. You have to make the closure of the fascia. But for the laparoscopic incisional hernia repair, it is a -- still a question and laparoscopic incisional hernia repair always means use of mesh.

Q. But does the type of mesh that you use bear on the answer to that question?

A. It is not specifically differentiated what type of mesh you are using.

Q. Okay. The next study you're working on is the study with knockout mice where you're studying genetics in the activation of a cellular response with a camera?

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A. Yes.

Q. And as I understood your description, the use of this specific strain of mice allows you to analyze the inflammatory response associated with certain meshes by just solely using a camera; is that correct?

A. Yes.

Q. Okay. Is this the first time you've used this type of analysis in mice with mesh?

A. I think this is the first time in the world that someone is using these type of mice for the analysis of the local inflammatory foreign body reaction.

Q. Okay. And how many mice were involved?

A. Overall, I think that we have three different strains of mice. We have -- overall, we have five different materials. You have several time points. 100, 120.

Q. How many different kinds of mesh were used with the mice?

A. We had four different meshes.

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Q. And what four different meshes did you test?
A. As a control for a material where we know that we have a significant intense inflammatory reaction, we used polypropylene as a --
Q. Any specific polypropylene?
A. It is a polypropylene -- all these meshes have been provided by the FEG here.
Q. Okay.
A. They are partner in this project, official partner in this project.
Q. Okay.
A. So they provided this polypropylene structure for us to see -- or because there it is more likely to see some inflammation. We know this and, therefore, we wanted to check whether this is -- whether we can see a sufficient signal there, that was the first question. Is it possible to see a signal there and, therefore, we took a material where we know that we have an intense inflammatory reaction and that was

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polypropylene.
For comparison, we immediate -- or in the beginning we -- that was the first step in this project was to use polypropylene. Then we have to look whether a signal occurs after one day, three days, seven days, 11 days because we didn't know when the maximum signal occurs. That was the first step to look what happens.
Next is when we have identified that there is a signal, where is the maximum of the signal that we compared it to PVDF, whether there is a difference of the intensity of the luminescence in all strains, in which strains, at what day and so. And the subsequent step of this project was that we wanted to reduce the inflammatory reaction by coating and, therefore, we made a coating of the PVDF mesh with a collagen spacer and two drugs, one is a spironolactone and the other was a steroid.
Q. There's three meshes.
Is there a fourth mesh that you tested?

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A. No, it was control collagen, it was coating 1, coating 2, polypropylene and PVDF.
Q. I see. Thank you.
A. So five, I think.
Q. And did you conduct the study with the knockout mice that you're describing --
A. Not really. I have to correct. It is not a knock out because not a gene is knocked out. It is a transgenic mice because they got additionally some genes which makes this luminescence.
Q. Do you have a short name that you give to this study that I can use? Is it the genetic study?
A. It is luminescence. What we are measuring is luminescence.
Q. So it's the luminescence study?
A. Study.
Q. For this luminescence study, is this done pursuant to a grant from FEG?
A. No. It's done by grant, as I told you, from North Rhine-Westphalia and the

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European Union.
Q. But FEG supplied the materials?
A. Yes. We -- yeah.
Q. Does FEG provide any financial assistance to the study?
A. No. They -- I have to pay them for providing these materials and for providing this coating.
Q. Okay.
A. And the people from North Rhine-Westphalia which makes the organization of this grant they asked me why this is necessary and whether I ask other manufacturers if they can provide the material cheaper, and I had to tell them there aren't any other manufacturer that are able to make a coating of these materials.
Q. Why did you choose to study PVDF?
A. Since 1998, 1998, we are convinced -- we are working -- we are convinced that PVDF is a superior material, and since 1998, I didn't saw any literature convincing me from a -- or bringing me to

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another opinion to this and, therefore, we still are convinced that PVDF is the best and we want to work with the best material.

Q. And are you compensated in any way for the work that you're doing on the luminescence study in addition to the compensation you receive at the university?

A. No.

Q. The last study I think you mentioned dealt with the German registry of meshes, and you're trying to analyze the impact of mesh materials and their complications by data in the registry; is that correct?

A. Yeah.

Q. Is that study underway, completed? What stage are you?

A. We're at the beginning.

Q. Okay.

A. Professor Köckerling asked me whether it is possible to do so because he knows the classification and then to go further on to combine this one and, therefore, he asked me and I provided some

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steps how to make this analysis and last week we was in South Africa on a conference, but I'm waiting daily on his phone so that we can sit together and discuss further steps.

Q. And the next steps will be to design the methodology for the appropriate analysis of this data?

A. It is -- the main step is that we have to learn -- I see severe or I see some difficulties to make an adequate analysis of the data of a registry. It's not so simple. We have to make some significant input in this. We have to work on it to find the best way to analyze these data in principle and at the occasion of these specific registry in Germany for hernia.

Q. Doctor, I've read some of your work and the work of others on the idea of a registry and one of the things that I've seen is the need for some sort of identification or data card.

Is that something that you advocate for registries?

A. I would prefer if you can

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specify what you're thinking as --

Q. Some template of information that comes with each hernia or mesh implant so that the registry can use the data to analyze the issues that you've described. Did you see a need for that, a uniform identity card or some sort of descriptive information at the time of the implant so that you can make a meaningful analysis of the data at a later point?

A. We had -- we're in the process of discussing all of this. We had a lot of discussions about it just to give the option to identify the mesh that has been implanted and to place this ID card in the document, in the records of the patient. It is not -- it will not help a lot. It will make -- it is already done in Germany you can -- if you take the records of any patient, you can see what implant has been used in this specific patient.

This will not help to learn what are the complications.

Q. What do you need to add to the

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registry to help you learn about the complications?

A. First of all, I -- yeah, first of all, you have to be very careful or you have to define very carefully what type of a parameters you're going to use to reflect the specific condition of the surgeon, of the patient and of the material -- of the mesh material there. So you have to define a certain number of parameters and one of the questions, for example, is whether you include in these parameters the weight of a mesh material, is it a worthful, helpful information, yes or not. Or do you have to use some coating, say, light-weight below a range of 35 gram or something like this. There are several attempts to do so.

So for the organization of the registry, you have to work on the parameters, you have to work on the follow-up, you have to provide the opportunity that when after three, four years an infection occurs that it is -- this information is included into the registry as well. So all this together has

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been there and then you need some mathematics, good methods to define the best interpretation of this data.

Q. Is the goal of your work with -- is it Professor Köckerling did I write that down write?

A. Professor Köckerling.

Q. Is the goal of your work with Professor Köckerling to identify the best way to gather the company data so that you can make the necessary analysis to learn about the complications associated with mesh?

A. To go a step further on this process to learn from registries and what we already may learn from our present data that we have. He has already 100,000 records from patients with hernia and maybe we can learn something from this. But I'm sure as science usually, we have to work on it.

Q. Okay.

A. And it will take some time.

Q. And is the goal of this study to figure out the best way to make use of the data that you have and to make better use of

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the data you develop in the future?

A. I think it -- I agree to this. It's a dynamic process.

MR. THOMAS: Let's take a break.

MR. ANDERSON: Okay.

(Off the record at 10:10 a.m.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, who is working with you on the luminescence study?

A. On the luminescence study, it was a Dr. Fet. She was the scientist, and it was a technical assistant who made some additional histological stainings because afterwards when the study finished, we took some tissue samples to correlate then to what we have seen with the luminescence signal. We have some help from the animal clinics there to take care of this. And I have to add, as coauthor, there has been two guys from the Institute for Anatomy, they provided -- they brought these three transgenic mice to Aachen and, therefore, this was their technology to make this

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measurement of the luminescence there, and in collaboration we were able to use their mice and their technology to make this light analysis there.

Q. Who designed the luminescence study?

A. Mainly it is my -- it has been my idea to do this and to use these mice and then for the -- all of the details, we all together discussed it with all of the participants there.

Q. And the coauthors who supplied the mice, what are their names?

A. Wruck, W-r-u-c-k, is one, and the other one is Pufe, P-u-f-e.

Q. And what are their specialties or disciplines?

A. Professor Pufe is head of an Institute for Anatomy and Dr. Wruck is one of his coworkers in this institute.

Q. Okay.

A. And they are dealing with molecule or changes in cells.

Q. As you probably know, earlier

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this week, I had the opportunity to talk to Dr. Klosterhalfen for a couple of days.

A. Yes.

Q. Have you spoken to Dr. Klosterhalfen about his deposition?

A. No.

Q. During his deposition, Dr. Klosterhalfen said that the FEG is working on a new mesh for the use in the pelvic floor.

Are you familiar with the FEG's project for a new mesh in the pelvic floor?

A. I am familiar with some idea, some projects they are working on and -- but not in the details of these projects. I am basically informed about the projects we still have together so.

Q. What projects do you still have with FEG today?

A. We have mainly, apart from this project with the luminescence mice where we did not apply for this grant together, but we have two projects that we have been working on that are granted. The first project is

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dealing with -- to allow the mesh to be detected in the magnetic resonance imaging, the MRI, and, therefore, we included some feral particle into -- during the extrusion of the filament, that it's necessary to do it during the extrusion of the filaments, these particles are added there and then these fibers are used for mesh construction and then these meshes can be visualized in human -- in living -- in living -- not things. In living animals or humans. In vivo so you can see it.

This visualization, there are a couple of following projects looking to what happens to the meshes after implantation by use of this one. This is one.

Q. What's the benefit of being able to see the mesh in vivo with these iron particles?

A. It is enormous.

So, first of all, if you want -- some of these advantages are if you have a complication, if you have a recurrence, if you have an infection or so,

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up to now you're forced to make a surgical revision because there is no good way to visualize the mesh, what happens to the mesh. So in case of any complications, you can verify whether there's a correct position of the mesh device.

Second is if you made an implantation there and you have the feeling that it's okay during the operation, we usually have the feeling that it is okay when we left the OR, and then you make an MRI two days later, sometimes you will be surprised what happens to the device there. Where the configuration changes, we are -- meanwhile we are even able to identify the pores.

So it helps a lot to get an impression what happens to the device, to the three-dimensional configuration of the device after use in humans. Even you can objectify shrinkage, degree, extents of shrinkage, extent of migration after some time.

So we are convinced that it is a very important step to, first of all, for the quality control of our surgery, that it

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helps for the diagnosis of complication and for the development of meshes, it will be very, very, very helpful. This is one.

Q. What's the other project you're working on?

A. The other project is together with the institute for textile technique and with the radiology and with the animal clinic it is the question whether it is possible to use elastic polymers for the use of constructions. Mainly if you have the problem that it is not tension free, there is tension, there are some forces, you need some elasticity, some stretchability. We -- yeah. We can discuss all of these problems in detail, I'm sure we will do so.

But the question is whether it is possible to use an elastic polymer for the construction of a mesh and to get first ideas what happens when using them in tissue.

Q. In the projects that you've worked on the last year for FEG, who is the primary contact that you've had there?

A. There is always -- for both of

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these projects, there are mainly three, four people that are working in the FEG mainly on these projects. It is a very small company so it doesn't have the --

Q. Who are they?

A. Dr. Mullen always, Dr. Obolensky, these are the two that are frequently involved, and there is Mr. Glazer, one again, and -- yeah.

Q. In the last year, have you had occasion to meet at FEG along with Dr. Klosterhalfen to discuss FEG projects?

A. In the last year, it was Klosterhalfen at the FEG together. I really cannot remember. The year before we have several meetings there, I know, at the occasion of this video film, but last year it is not -- Klosterhalfen is so busy in his institute and I'm busy with my university, I cannot remember that we met there.

Q. Okay. Did you talk on a conference call with the people at FEG and yourself and Professor Klosterhalfen about issues that you were analyzing for FEG?

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MR. ANDERSON: In the last year?
MR. THOMAS: In the last year.
MR. ANDERSON: Thanks.
THE WITNESS: Do you mean that -- sorry, maybe I didn't understand.
Was it -- did I meet with Klosterhalfen or the FEG or did you think of meetings where we all are together at one place?
QUESTIONS BY MR. THOMAS:
Q. Either together in one place or on the telephone together. Either one.
A. With Klosterhalfen sometimes depending on the data we got from the projects, at least every two weeks, once a month we had some phone calls, some exchange, sometimes I'm driving to Düren. It is -- no, he never came to the university so I usually go over there to him or at his home place here and there we discussed it or during the meetings. So he took me to the -- so he brought me to the conference to Professor

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Yaeger so we had two hours time to discuss all of this.
With the FEG, I think -- or if I estimate, there are two times a week -- yeah, two times a week we have some short communications. We regularly -- in these projects, we have learned that it is necessary to have regular meetings to make protocol, you have to define some problems and you have to define the question that have to be addressed. So there are regularly meetings once a month for each of these projects.
Q. Okay.
A. Usually at the university.
Q. And so you have meetings once a month and you talk to them about twice a week about the project on the --
A. Depends. Sometimes four weeks not, but some -- yeah.
Q. Okay.
A. Usually it's -- there is something that has to be discussed.
Q. Okay. Now, Professor

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Klosterhalfen told us this weekend about a video that he uses in his presentations.
Did you assist in the preparation of that video?
A. Yes. Yes. It was -- it is the idea mainly behind -- I was just contacted by, I think, Dr. Obolensky that they wanted to visualize the slides that Bernd created. You know it, it was used by Ethicon as well, where the macrophages are sitting to the cells and what happens during the foreign body reaction.
So he made -- he prepared, I think, about 2000 or even maybe before he prepared these slides with PowerPoint to illustrate what happens during the start of the foreign body reaction. And a lot of people -- it was difficult to explain it to surgeons and, therefore, the idea was to make a short film there, and there was a small company here in Aachen that offered this opportunity and this was the first time to try to realize to make a film showing the foreign body reaction. And the film people

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doesn't know what is a cell.
They looked at Google images, but it was very difficult for them to get the information what happens there. Dr. Obolensky is an engineer. The question what is a size of the macrophage, what is the size of the morphology of a fiber blast, it's too much for them, and, therefore, he needs to -- that we have to define some measurements and that we have to check whether this was correct what was shown and, therefore, we had some meetings looking to ten seconds of a video sitting there and discussing one hour for ten seconds. It was -- yeah, but it was -- afterwards we were very satisfied because then we can use some parts just to illustrate what happens there.
Q. Do you use the video in your presentations?
A. Sometimes. Sometimes -- when I was asked to give a presentation to explain foreign body reaction, it is very helpful to take a sequence of one minute there and to explain it to the people. It is very helpful

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for them.
Q. What contribution did you have to the film other than the meetings that you've described?
A. Contributions? When are you thinking of?
Q. Are you part of the film?
A. I'm -- there are only cells on the film so --
Q. I've not seen it.
A. I'm not part of the film.
Q. Not your cells?
A. No. It's all -- it's all in animation. There is no real cell there.
Q. Okay. Who prepared the animation?
A. It's a company here. A small two guys here trying to survive in this society here.
Q. So just trying to understand, you provided information to this company, they worked on this animation?
A. Yes.
Q. And then you and Professor

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Klosterhalfen reviewed what they did and changed it as necessary so it was a fair preparation of what you're trying to show.
Is that fair?
A. That -- I think that is correct, yeah.
Q. All right.
A. So we sometimes, just as an example, we have to enhance the size of some cell and put it lower than and to say that the vessels are coming after day seven and not after -- so all of these details are coming from both of us.
Q. And this is an animation, I think you said?
A. If animation is a correct word. It's just computer work.
Q. I've not seen it. That's why I don't know. I didn't know if you were in it and holding things up or what. So that --
A. Yeah, but I think it's free. Everyone can look at it.
Q. I guess we'll see.
How much time did you spend

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working on the film?
A. Maybe it was five sessions.
Q. Okay. You've had a busy year.
Have you done anything else professionally of significance -- I'm just trying to think of big things that you've done in the last year, other than the things that you've described to me in the last little bit of time.
A. I'm in the review board for the university to -- we have an internal grant system where we got a lot of applications, and I'm in the group that has to review these grants. So this takes some time. I have to pass exam, so when finishing the medical studies, you have to pass a final exam there, and I have a group or I'm leader of a group for making this exam. This is two times a year I have to do so. This takes some time.
Q. Okay.
A. I have to review a lot. It takes time to review other -- for other journals and so...
Q. How much time did you spend

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preparing your report in this case?
MR. ANDERSON: Would you want this?
MR. THOMAS: That would be great.
(Klinge Exhibit 1 marked for identification.)
MR. ANDERSON: And that's just I'm handing you his invoice that's up through the end of October 31.
QUESTIONS BY MR. THOMAS:
Q. Okay. Doctor, I've handed you what's been marked as Deposition Exhibit Number 1, Klinge Deposition Exhibit Number 1. Mr. Anderson just gave this to me. This is an invoice that you sent to Mr. Anderson for the time that you've spent in this matter; is that correct?
A. Yeah.
Q. Now, does Exhibit Number 1 cover the time that you've spent on this matter learning the information that you've been provided and preparing your expert

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report?
A. Yes.
Q. Does it include any time preparing for this deposition?
MR. ANDERSON: It just goes through October.
THE WITNESS: So we met here Tuesday, Wednesday so this is not included in that.
QUESTIONS BY MR. THOMAS:
Q. Okay. And so the time that you've spent in November has been the time that you've spent with counsel preparing for your deposition?
A. Yes.
Q. And you've met on Tuesday and Wednesday to prepare for the deposition?
A. Yes.
Q. How much time did you spend on Tuesday?
MR. ANDERSON: You need to see this over there?
MR. THOMAS: Pardon me?
MR. ANDERSON: Do you need to

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look at this --
MR. THOMAS: I am sorry, I just wanted him to have it.
MR. ANDERSON: No problem.
THE WITNESS: About six hours.
QUESTIONS BY MR. THOMAS:
Q. Each day?
A. Each day.
Q. Okay. And you continue to charge at the rate of $500 an hour?
A. Yes.
Q. Why do you laugh?
A. Yeah, it's an interesting question, yeah. I have to think about it.
Q. I don't understand.
MR. ANDERSON: Maybe he's going to change his bill after today. Maybe he'll --
THE WITNESS: It's a good idea. Thank you.
MR. ANDERSON: I think he interpreted it, "Are you going to continue to bill at $500 an hour," and he's like, "Oh, good idea, maybe I

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should charge more." That was the -- just teasing with you.
QUESTIONS BY MR. THOMAS:
Q. Is your salary at the university the same as it was last year?
A. We have a small increase. Annually we have a small increase to this, but roughly, it's in this range.
Q. Okay. Doctor, as a part of the deposition in this case you were asked to collect a bunch of documents.
What did you do to collect the documents that you have concerning your relationship with Ethicon?
MR. ANDERSON: And, Counsel, if I could just help address that with you. So very similar to the way that -- in response to the request that you had served and then with the multiple hearings with Judge Eifert, as we did with Dr. Klosterhalfen, we asked Dr. Klinge to try to go back and recover any documents that he had going back through his relationship

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with Ethicon into the '90s. And so he made a reasonable, diligent effort to try to get as many of those as he could, and as you know, we produced thousands of pages of documents in that regard.
In preparing him in talking about hard copies and things like that, he said there may be old hard copies somewhere at the hospital. So that was new information, he hadn't thought of it, so Mr. Thornburg went with him to the hospital and, in fact, there are some old paper copies as they dug through his information. We got those yesterday. We sent them to a copy center hoping that -- realizing you wouldn't have a chance to look at them, but at least to say in an effort to make sure we unturned every stone just like your team is trying to do over here with all of the hernia productions that have been rolled out, we wanted to make sure that we tried

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to capture everything for you.
Unlike maybe a Kinko's what we're used to, they said it would take until Saturday to get these documents produced for us. So they're in German. They go back to, like, VYPRO and things like that. But certainly we will -- when we get those copies, we're going to send them to you. If in looking at those -- I mean, I don't think that they're going to provide you with some significant level of new information beyond the -- it's my impression -- that they won't provide you with any significant level of information beyond all of the things that he's produced thus far.
However, if in looking at those, you determine that there's, "Boy, those were -- there's a couple of burning issues in there and had I had them before, I certainly would have liked to have asked him some questions on it," then you and I can

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speak about that once you've had an opportunity to look at them and we'll come up with a fair and reasonable approach to allow you to do what you need to as you see fit, if, in fact, there is any more information.
Is that fair?
MR. THOMAS: Sure.
MR. ANDERSON: Okay.
MR. THOMAS: I appreciate it.
MR. ANDERSON: Sure.
QUESTIONS BY MR. THOMAS:
Q. What is the volume of additional documents that you found in the last couple of days?
A. The value?
Q. Well, how many?
MR. ANDERSON: I would say hundreds of pages, not thousands. Maybe a few hundred in looking at maybe this. Maybe that.
QUESTIONS BY MR. THOMAS:
Q. What kinds of documents did you retrieve from the hospital in the last couple

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of days?
A. We started to work in this field in 1994 and this was a time without internet. I was one of the first who has a computer so I had these big floppies from IBM and so no one is able to read them any longer.
But at that time, we had some paperwork. Then it started with e-mail, I think, in 1998 or so that we started to make these e-mails, sometimes a copy/paste there, and we have to switch all of these e-mail accounts a little bit.
So all of these documents are some incomplete printouts of this time period in this field. Something has to do with the VYPRO -- international VYPRO study where we produced some hard copies. But all in all, these are documents where I'm sure that we have shared them with the people from Norderstedt, Ethicon Norderstedt. I'm -- I don't expect that there is any page there that is not known by Dr. Engel, Dr. Holste and these guys.

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Q. Okay. Doctor, when you conducted your search the first time, where did you look for documents?
A. Mainly, I have been looking on my computer.
Q. How old is your computer? How long have you had it?
A. The last critical crash I had in 2000 where I lost some data and the next disappointing experience was when we have to -- when I had to change from Netscape to Outlook. So the e-mails until 2005, I lost several of them. I could recover some of them, and for some times they are doubled or three times on the computer because I never worked on it to make a chronic {sic} of the e-mails at that time.
Q. So do you feel like you captured all of the documents that you had on your computer back to 2005?
A. Even longer. There are some documents, some manuscripts, some e-mails, some attachments that are from the time period before.

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Q. I understand that.
A. Some sheets --
Q. I guess I'm trying to break it down. I thought I understood you to say the last computer problem you had was 2005.
So are you pretty confident that what you gathered from 2005 forward is a complete set of the documents that you have?
A. I was asked to send you all documents for the time period when I was consulting or were in direct --
Q. I understand that. And I think you've told me --
A. You always --
Q. For the period 2000 to 2005, you've done your best, from the period of 2000 to 2005, there may be some documents that were lost in the changeover of your computer system, is that fair?
A. I cannot exclude that some of the e-mails, mainly e-mails, are lost.
Q. And prior to 2000, there were other documents that you had a computer problem in 2000, you may have lost some

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documents with your computer problems in 2000.
Is that fair?
A. Yes.
Q. Okay. So you made your best efforts to recover whatever computer documents that you have stored on your current computer, correct?
A. Yes.
Q. You've already described or Mr. Anderson has described efforts that you made to find hard copies that exist at the hospital.
Do you have any hard copies in your possession either in your home or your office that you haven't produced in this litigation?
A. No. They remind me to have another look to all of these documents. They are in my trunk.
MR. ANDERSON: Cabinet.
THE WITNESS: Cabinet. They're very back with the dust of ten centimeters on top, and so we worked

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on it and to find it and you get it.
QUESTIONS BY MR. THOMAS:
Q. Okay.
A. And I'm sure you will be happy with it.
Q. Somebody will.
Doctor, I have tried to identify the documents that have been produced to me in German. I need your help.
A. Was it a sharp decision for the US to talk -- that your language is English? I've learned the history.
Q. You know what, that's one decision I have no responsibility for. It's not my fault.
A. Yes. Of course, but looking backwards it may be a disadvantage.
Q. Some people may think so.
A. For you. For your specific condition in this specific location.
Q. Today.
A. Today. That's correct.
Q. Wait until next week.
A. Please mark that we are in

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agreement, in full agreement.
Q. Doctor, I agree with you more than you know.
(Klinge Exhibit 2 marked for identification.)
QUESTIONS BY MR. THOMAS:
Q. Let me show you Deposition Exhibit Number 2.
What is Deposition Exhibit Number 2?
A. That is a draft of a contract between Ethicon Hamburg and the university, in particular, the surgical department there. It is not the first one. It is a -- one of the subsequent proposals, contracts there. This is the official contract between Ethicon and the surgical department, and there is mentioned what has to be done by the surgical department.
So on page 2, for example, you have to optimize mesh structures as hernia device on basis of large pore meshes. So we're asked to do so. We should do -- use long-term absorbable materials for the use in

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pediatric surgery. We should look at mesh materials for antimicrobial effectivity there, and we should look or develop meshes for temporary closures of the abdominal wall. And there has been to each of these points, there has been some specifically proposals, projects by some of my colleagues. And you see later on at A, at B, there are some more details to these projects, but during the following years, this is -- try to realize all of these working projects.

And there are others conditions. The costs. So the money that Ethicon prepared there. It's listed on here. It's 100,021 -- 120,000 Euros per year for three years, and it is arranged a confidence -- a level of confidence and it is fixed what happens to patents and so on.

That is standard -- a routine, not a standard, maybe I've learned that there is a difference in the meaning. It's a routine form that has been arranged in agreement with the administration at our university.

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Q. You told me that Exhibit 2 was a draft contract.

When was this draft discussed, if you remember?

A. It should be 2001 to 2002.

Q. Was there ultimately a final contract signed by the parties that people agreed to?

A. Yes.

If you look to my reports, somewhere there is listed of the projects with external financiation, and there I have listed in a table the project that have been done with Ethicon. And there you can find when this project started and, therefore, there will be a definitive contract. One -- one will be at the administration, one is in the hands of Professor Schumpelick and one will be at Hamburg Norderstedt.

Q. Do you have a final --

A. No.

Q. Let me finish my question.

Do you have a final copy of the draft contract which is Exhibit 2? Do you

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have a final signed copy of that agreement?

A. A final of the draft copy?

Q. That's a bad question.

A. Yeah.

Q. Do you have the document that resulted from Exhibit 2 that the parties ultimately signed as a contract?

A. No.

Q. Thank you.

During the time that you had a research relationship with Ethicon, was it your understanding that Ethicon and the clinic had a contract that governed their relationship?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: I know from the first contract in '94, that there is -- that there has to be and that there is an official contract when industry wants to make research with the university and this has to be officially checked by the administration there and, yeah, and I

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know that this happens and it has to be signed by the head of the university and it has to be signed by the head of the surgical department and it has to be signed by Ethicon.

QUESTIONS BY MR. THOMAS:

Q. Okay.

A. Not by me.

Q. But whatever those contracts are, you don't have copies of the signed versions; is that true?

A. I don't have copies of it, but I know -- I have seen at that time the final version that they exist, yes.

Q. Okay.

A. Because I had to send them and to bring them.

Q. You had to bring them?

A. I brought them to the administration and to Schumpelick and had to take care that they are signed and --

Q. If you wanted to get a copy of that signed contract at the hospital, do you know where to go get it?

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A. I know where to ask for it. I have some doubts because the head of the surgical department changed so a lot of these older documents will be somewhere at someplace. Probably I would first ask the people in Hamburg Norderstedt.

(Klinge Exhibit 3 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Let me hand you now what I've marked as Deposition Exhibit Number 3.

What is Deposition Exhibit Number 3?

A. If you have a project with industry and you have this research contract, then it is clear that the industry or that the supporter or whatever it is, that they provide some resources, some money for these studies and the administration needs to place the money somewhere and, therefore, it is -- they need an announcement of this third-party project and this is the announcement of a specific study we did with Ethicon that is the closure of laparotomy with a panicle

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suture. It has been a prospective randomized trial that we performed for Ethicon Norderstedt in the time from 1997 to 1999 and so we -- there is, of course, some of this research contract and this additionally is the announcement for the administration.

Q. Okay. So is the money in Exhibit 3 for this specific project in addition to the money that Ethicon paid to the clinic?

A. Yes.

Q. Thank you.

So at this time, Ethicon provided money to the clinic on a yearly basis in a flat sum and then paid additional sums for work that was outside the contract; is that right? Is that correct?

A. Outside of this contract, but it is always covered by some contract. But there has been some additional contracts, some overlapping periods of some different projects.

(Klinge Exhibit 4 marked for identification.)

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QUESTIONS BY MR. THOMAS:

Q. Doctor, I've handed you now what's been marked as Deposition Exhibit Number 4.

What is Exhibit 4?

A. It is an agreement for confidence that we -- yeah. To be confident about -- yeah. Confidence agreement, I think that is --

Q. Confidentiality agreement?

A. Yeah.

Q. Okay. And this obviously was a draft document.

Was this document ever finalized and signed?

A. I'm sure it will because the people in Hamburg, they are very careful to have this back in a signed version.

Q. When -- what's the date when this negotiation of this draft document was going on?

A. I think this is just restricted -- I have -- I have got an invitation to go to Hamburg in a working

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group there, and I was asked to present the results of our studies there and discussed with some people from R&D, and I remember there has been someone from the US as well and I -- I remember -- if I look to the last page, it is on the occasion of a meeting for developing of new meshes there. Just for this meeting. This is just restricted a confidentiality for this specific meeting there.

Q. Okay.

A. But I don't remember any more details.

Q. Do you know when?

A. Maybe around 2000.

Q. Is that all that you remember about this document?

A. Yes, we -- there are so many documents about confidentiality agreement and --

Q. I understand. And I'm doing the best I can, too, because I have no idea what I'm looking at. This is my bad day, you told me.

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A. No. No. No. Definitely not.
(Klinge Exhibit 5 marked for identification.)
QUESTIONS BY MR. THOMAS:
Q. Doctor, let me show you what I've marked as Deposition Exhibit Number 5.
What is Deposition Exhibit Number 5?
A. That is a contract between Ethicon and me. There has been in the time period of 2000. 2000, there has been a discussion whether it is possible or necessary that me and, in particularly, Professor Klosterhalfen get some further support to keep on our working. And then all of the money went directly to the university or to the surgical department or whatever. So in 2000, there was a discussion that we would like to participate a little bit when we are asked to spend so much effort and time in these developments, and we got a draft from Ethicon Norderstedt that they offered to us for the time period of five years royalties of .5 percent. And they offered

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this with some additional remarks about the patents and some restrictions of what is allowed and what is not allowed and so this was -- this is the draft of it.
Q. Do you know whether this is the document that you finally signed?
A. I have no doubt that this is the one.
Q. It is or it is not?
A. Otherwise there should be draft on it.
Q. I don't have a signed copy of it.
A. It is not a copy where I signed it.
Q. Okay.
A. So --
Q. At some point in time, do you recall signing a document like Exhibit 5?
A. Yes. Yes.
Q. Did you retain --
A. I have no doubt that this is the one we signed.
Q. Okay. I don't want you to read

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it word for word for me, but just tell me what each category speaks to, please.
A. First of all, here -- so what may be interesting for you, they refer to a -- to ongoing research activities with the technical university starting in July 1995 for them, that is the first sentence.
Second sentence is they mention that they already had -- were the owner of all relevant patents in this -- in this field.
Q. And we're referring now specifically to VYPRO?
A. They don't -- they just said they have all rights at the invention related to this topic.
Q. Okay. That's fine.
A. There's no specifically that there is a VYPRO patent or not.
The next is that both partners have worked on it and has introduced some efforts to this. And the agreement they said that -- the partner agreed that they will contribute some knowledge for the development

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in these -- in these projects. That the partners -- if Ethicon want to know something, that the partner said, I will give you the answer to this and will help you to answer it.
And there is in point 1.3, there is a sentence that the partner, that makes me, that we never will claim afterwards whether my name should have been included in the patent.
Q. I see.
A. This is a very tricky situation. I'm not expert in German international patent laws, but the fact is that the VYPRO patent for Europe and for the US, they included a lot of these phrases that we produced, but we are not named as an inventor in these. And this may be disputable, but we agreed in this -- I'm not sure whether the limitation of this contract for five years means that we are not allowed to claim this within the five years or whether we have to accept it lifelong. So I'm not sure.

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Q. Okay.
A. But this is the --
Q. Does the next section --
A. Compensation is €120,000 and then for five years, we got royalties. So this is the right of 1.5 percent.
Q. 1.5 percent of what?
A. Of the internal -- the internal costs, not without the -- so the value of the meshes they sold in this time period.
Q. Okay. For all meshes?
A. It is not specified here. It is not specified. So later on, I know that it -- that they took the VYPRO, but they took as well VYPRO II and ULTRAPRO™.
Q. Okay. So you --
A. It is not limited to VYPRO.
Q. So you had VYPRO I, VYPRO II and ULTRAPRO™ for which you were paid royalties?
A. Yes.
Q. Okay.
A. So this was what I learned from the letters I got from Ethicon.

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Q. Okay. Is that pretty much the substance of this contract?
Is there anything else of significance to you in the contract?
A. Yeah, I think that is -- and I'm not -- I'm not allowed to talk to anyone else about this agreement. So -- but I was told that Ethicon asked for this agreement and, therefore, I provided it, but otherwise, I would -- I don't hope that I will get in conflict by someone else because I open it to a third --
Q. You won't. We arranged that.
A. Okay. Please --
Q. She takes down every word, and she's very good.
A. That is so fine.
Q. Now, I understand from your last deposition, I don't want to replow this ground, but sometime in 2005, there was a discussion about negotiating a new contract?
A. Yes.
Q. Did you produce any draft contracts to me --

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A. Yes. There is a draft.
Q. Maybe this is it.
(Klinge Exhibit 6 marked for identification.)
QUESTIONS BY MR. THOMAS:
Q. Let me show you what I've marked as Deposition Exhibit Number 6.
What is Deposition Exhibit Number 6?
A. This is a -- so after the first -- after this contract stopped in 2005, then we had some discussions how to continue our collaboration, our work, and this was provided in 2009. It was a draft of a possible contract consulting agreement, how to make the further collaboration.
Q. Now, last time we were together, you testified that the reason why you weren't interested in the contract was because Ethicon would not allow you to work with other manufacturers, that's what I recall.
Is that right?
A. That is -- that is one aspect

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of this.
Q. Okay.
A. There are several arguments and there are always some pros and some cons, but overall, it is just consulting. It is some money for some time period where you were asked and this to the prize that you're not allowed to do any other work there.
Q. Okay.
A. And I'm not interested in being a tester for devices or a consulter, just being consulting. I wanted to work on it.
This would mean when I sign this, I may earn some money for some consulting activities, but I'm limited in my scientific work. And there's no option to work scientifically in some projects. That was not included in this and that is my major criticism to this.
Q. Exhibit 6 was a document that you produced to us.
Is that the only draft that you were able to find?
A. I'm sure that in the documents

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I sent you there are several versions of this draft because there are some comments. It has to be checked by the administration, by the legal offices in the administration at the university hospital as well. So there was a little bit attempt to improve it, but finally it was not acceptable by me.

Q. Is it your recollection in the documents that you produced to counsel that were given to us that there should be more versions than just Exhibit 6?

A. Here you see there are some corrections.

Q. Yeah.

A. Some comments.

Q. My question is really a very simple one, and I don't mean to interrupt you.

Do you think there's more than one draft of the contract in the documents that you gave Mr. Anderson?

A. I would expect there's some version, at least the original version without these comments there. I would expect

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that.

Q. There very well may be.

For Exhibit Number 5, who at Ethicon did you deal with to negotiate this contract?

MR. ANDERSON: Objection. Form.

THE WITNESS: The two people at that time that was Dr. Engel, he was the head of the R&D in Ethicon Norderstedt, and the man finally signed was Dr. Schmitt. He was the head of Ethicon Norderstedt at that time. But the e-mails, communication, they were done with the head of the R&D department. I'm not sure whether it was Dr. Engel or Dr. Hoepffner. Dr. Hoepffner was the predecessor before Dr. Engel. There was Dr. Hoepffner. If this is -- the time already with Dr. Engel, I assume it is. So these are the two.

Q. Who within the Aachen group received a contract like this to share in the

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royalties from the sale of Ethicon meshes?

A. It is -- such a contract was given only to Professor Klosterhalfen and me.

Q. Do you know whether Professor Schumpelick received any kind of contract?

A. I know that he has some contract either or the time before. When it start, I don't know, but I know that he has a specific contract there, and at that time, it was told that it's about two percent.

Q. Did you know that at the time that you were negotiating this contract with Ethicon in 2000 that Professor Schumpelick was receiving two percent of sales?

A. We had the knowledge. We didn't see the contract, but we had the knowledge that he got some royalties for all of the work, yeah.

Q. Did you and Professor Klosterhalfen negotiate these contracts together?

A. Negotiate in the meaning -- so I cannot remember that either Bernd or me changed anything. It was some legal thing as

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to be with a -- with the administration, they have to check the legal things, whether it's allowed to do so as an employee or so. And I'm sure we got similar draft.

Q. Did you and Dr. Klosterhalfen talk about it between yourselves before you agreed to it?

A. Yes, of course.

Q. And you and Dr. Klosterhalfen were satisfied at the time that that was a fair contract for you?

A. It was the best we could and it was the first time to our knowledge that someone has got this privilege.

Q. Okay. Did Ethicon comply with its obligations under this agreement with you, Exhibit 5?

A. Comply means fulfill all these obligations?

Q. Yes.

A. Yes. No complaint about it.

Q. Exhibit Number 6, which is the next agreement, who did you deal with in your -- for your discussions about the

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contract in 2009?
A. Whom do you deal? With whom I discussed it?
Q. That's right. At Ethicon.
A. Ethicon, it was a -- I got this mail with this attachment from Brigitte Hellhammer because when looking to all of the documents, I by chance saw this e-mail from Brigitte Hellhammer, but she forgot it for some time, but then she remind me and she sent me this contract.
Q. Was Dr. Hellhammer the person who approached you about the contract?
A. No. It was a discussion with Boris Batke. We had discussions with Dr. Engel, but then later he left some times Ethicon. Then I had some discussions about Boris -- with Boris Batke how to continue this work, how to -- how to continue the activities of the so-called Aachen group and then we had some discussions with the chairpersons from Ethicon. At some conferences, we had some meetings and to check whether there are some options to work

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together and what are the expectations, what has been going wrong in the past and why. So a lot of these discussions, but it started with Boris Batke and I think it was Dr. Engel and then they provided this one.
Q. Okay. What did you understand from your conversation with Ethicon about what had gone wrong in the past?
A. There are still many aspects we still do not understand why this sometime stopped. I didn't get a good explanation why this happened.
Q. Why what happened?
A. If you look to the records, we have a collaboration with Ethicon almost daily. We have some phone calls, some mails, we have an exchange of data, we have questions, we presented a lot of these things, we have a lot of discussions, they have a lot of questions, we have a lot of answers, and with the VYPRO, we had for the first time a medical device with a -- with a reliable scientific story behind it. It is the first time I know that you have a medical

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device development with this science as background information there.
And this was offered to the market with all of the explanations, with all of the scientific support and it was tremendously successful for all the speakers, including Professor Schumpelick who for the first years presented all of these messages. It was successful for Ethicon as well.
So until 2002, 2003, we thought that it is possible to continue this way of working to make the scientific support from the university to have a manufacturer transporting, transferring this knowledge to the patient there and work together to the benefit of all. Until 2002, 2003, we have been -- we hope that it could be realized, but then it stopped.
Q. Why did it stop?
A. I don't know full details, but I can show you that there are a lot of -- or I remember we have several working -- or meetings with this working group in Aachen there and even there it was discussed how we

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can revival -- no, we can revitalize the activity and productivity. But there's still open questions. I don't know whether you find someone who can give you a sufficient explanation for this.
Q. Okay.
A. Maybe you can ask -- one point of that point is we made this development with the German part of the R&D at Ethicon, and I cannot remember that there was any serious conflict that they said, no, that's not right. So we went the way to the ULTRAPRO™. Finally to the ULTRAPRO™. And I know that there always has some discussions with the part of Ethicon in the US. We had a visit from Barbolt here in Germany and he looked to the data of Klosterhalfen and said, "No, I don't believe anything of it. It's all mild to moderate," and then they disappeared again.
So we had the impression that there was some internal conflict in Ethicon between the US and the Germany, but I didn't have any serious information about this.

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But the people in Norderstedt, I'm sure in all of these meetings, they totally agreed to our way of thinking of a development of a medical device.

Q. When did it change?

A. It changed in 2001, 2002. It start to change in this time period.

Q. And how did it change?

MR. ANDERSON: Other than what he's already told you?

MR. THOMAS: Yes, but he's now given me a time frame of 2001, 2002.

QUESTIONS BY MR. THOMAS:

Q. Doctor, given your answer that there was a change in 2001, 2002, I want you to tell me how your day-to-day interactions with Ethicon changed.

A. Basically, I was at the beginning of this VYPRO story, and at that time, we have been sitting together sharing the ideas, discussing these ideas, sending some ideas with Dr. Hyntsch from Hamburg to Germany and then we got some first textiles. We made some measurements here. We sent the

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results to them back and then we made together decisions how to proceed, what to do and all of these discussions very, very open there.

And the first what -- the first experience where it was indicated that it changes was the manufacturing of the VYPRO II. The VYPRO II was an idea of Professor Schumpelick. He wanted to have a stiffer material and, therefore, he proposed to double the amount of Vicryl and suddenly -- for me, suddenly there appears the VYPRO II mesh material where they just doubled the amount of Vicryl.

If you look to the science and to the literature, Vicryl is increasing the inflammatory and fibrotic reaction to the tissue. So it was not a good idea to enhance the inflammatory and fibrotic reaction by doubling the amount of the Vicryl.

Q. And just so I understand, that was Professor Schumpelick's idea?

A. He had -- we had all several discussions about it, but just to see when

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they -- when the people from Ethicon are coming to Hamburg, eight persons are coming there, finally there was a meeting of Dr. Hoepffner, Dr. Engel with Professor Schumpelick up there out of this -- there was a working group and there is some -- the heads or the leading persons are meeting separately. And so this is not discussed in the entire group.

So then they appeared with these Vicryl II mesh.

Q. VYPRO II?

A. VYPRO II mesh.

And immediately there has been some publication from Professor Köckerling at that time in Hanover where he saw that the performance of the VYPRO II is poor. It's bad. And at that time Klosterhalfen met me, we wrote a letter to Dr. Engel and said that is -- we have to expect this. This poor performance of the VYPRO II.

But we have not been involved in any step of the decisions of the configuration of this mesh. And later on the

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ULTRAPRO™ was presented I think at a meeting at Suvretta for the first time. Again, we haven't been involved in the development. We switched to get -- to become a tester of some material that has been produced outside and that is -- that is complete different to the starting period.

Q. Did you -- strike that.

The letter that you wrote to Dr. Engel explaining to Dr. Engel that the problems with VYPRO II should have been expected, did you save a copy of that letter?

A. It is in the -- in the documents I provided to you.

Q. Great.

And did you review that in preparation for your deposition?

A. I saw this -- I know that we wrote this letter, and I found it when looking to all of these e-mails, attachments and documents, there some way was this letter.

Q. And is it from you and Dr. Klosterhalfen to Dr. Engel?

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A. Yes. We signed it, yeah.
Q. And it's in German?
A. It is in German.
Q. Do you remember the month and year when you wrote the letter?
A. 2000, 2001.
Q. Okay.
A. It was a -- we thought that it was -- it was somehow difficult for us to make such a statement there.
Q. Is it fair to understand that you wanted Dr. Engel to know that this was not the way you wanted the relationship to continue?
A. We wanted to inform him that there is a risk that the VYPRO I was a specific development with a specific scientific background, that this is not true for the VYPRO II, that there are some additional risks that we wanted to inform him. And if you look to the literature further on and I have learned by this litigation, there has been the use of VYPRO II in some regions of the body with not very

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satisfying results. And when I saw this letter, yeah, it is not very surprising.
Q. Other than the letter that you and Professor Klosterhalfen wrote to Dr. Engel, did you have communications with any other Ethicon people expressing your dissatisfaction about the way the VYPRO II matter was handled?
A. I don't recall. I recall this specific letter because this was an important decision for ourselves as well to make this letter. I know we had our discussions -- we had several discussions with these people during our meetings, the various topics, and I'm sure we presented the experimental results of the Vicryl to them as well, so in this regard, we discussed a lot about the disadvantages of Vicryl, and I am sure that this is the reason that the ULTRAPRO™ do not have the Vicryl any longer, but they switched to Monocryl.
Q. Why were you and Professor Klosterhalfen concerned about writing this letter to Dr. Engel?

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A. Because it -- no, we have a little bit afraid what are the results of going in opponent position to this. It is not very -- at least I'm not sure. I think it is not very well appreciated to get such a letter from two scientists from the university and, therefore, we several times think whether it was justified, whether we should be brave enough to do so and take the consequences. However, we did it.
Q. Was Professor Schumpelick aware that you and Dr. Klosterhalfen wrote a letter to Dr. Engel about VYPRO II?
A. We did not -- we didn't go to him and ask him whether we can do or we didn't inform him. We were independent scientists and this was our -- we were convinced of this fact and, therefore, we did it, but I'm sure he will be informed from Dr. Engel.
Q. Did you and Professor Klosterhalfen ever have discussions with Professor Schumpelick about the letter that you and Professor Klosterhalfen wrote to

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Dieter Engel about VYPRO II?
A. Not about the letter, but about the fact, the fact that we didn't like -- that we didn't think that Vicryl is a good material to be added to the meshes. That is -- that we discussed very, very clearly.
Q. Did he disagree with you?
A. Not on the basis of the facts.
Q. Why did he disagree with you?
A. He want to add a stiffer material. However --
Q. He's wrong?
A. Of course.
Q. Exactly.
Now, Doctor, Professor Schumpelick is trained as what, what's his specialty?
A. Professor Schumpelick, he's retired meanwhile in 2000 --
Q. I'm talking about at this time in 1990 --
A. At the time, he was the head of the surgical department at the university hospital, and he is one of the most famous

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person in hernia surgery, in the field of hernia surgery, and with the help of our work, he's very, very well-known in all of the discussions about mesh materials, and today he is the president of the European Hernia Society for -- elected last year for the next two years. And he's living in Hamburg so very close to the people in Norderstedt.

Q. At the time that you wrote -- you and Professor Klosterhalfen wrote this letter to Dr. Engel, was he the person who was the head of the Aachen group?

A. The official -- he was the official head of the surgical department.

Q. And as such --

A. The scientific group was mainly based on my activities there.

Q. Dr. Klinge, your activities with the scientific group at the university ultimately had to report to Professor Schumpelick, is that fair?

MR. ANDERSON: At what point in time?

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MR. THOMAS: At this time he wrote the letter.

MR. ANDERSON: Okay.

THE WITNESS: No, I didn't have to. No, I didn't have to make a report to Professor Schumpelick. He asked me what can be done. He mentioned some issues, some problems he got from all of the conferences where you're coming from and wanted to have some solutions, and my ability was to make some projects to make some questions, to make some study protocols there and then I collected people that are willing to take over this part of the project and so we -- I built up a network research to the topic of the mesh and then we put all of these documents together, make a PowerPoint presentation and then he goes to the conference and presented these -- all these results or he was an organizer of the Suvretta meetings, but we made all of the different

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presentations and put the messages, but he is organizing these meetings. That was his responsibility. But not that he controlled my science or so, that was not the way.

QUESTIONS BY MR. THOMAS:

Q. At the time that you and Professor Klosterhalfen wrote this letter to Dieter Engel at Ethicon suggesting that the VYPRO II mesh had some problems, was Professor Schumpelick your superior at the university?

A. Yes.

MR. ANDERSON: Been going about an hour and a half, a little more, want to take a little break?

MR. THOMAS: Take a break.

(Off the record at 11:41 a.m.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, we've talked about your search for documents and the large number of documents you've produced.

About how tall of a stack of documents did you find?

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A. The hard copies or the --

Q. Hard copy.

A. -- the electronic things when they're printed out?

Q. Did you produce it electronically, or did you produce them in hard copy or both?

MR. ANDERSON: As I was telling you before, the first batch that I sent you, it was actually in two batches that we were trying to get printed and stuff, those are the ones that I had him search his computer for, and the latter batch that I'm talking about as we were discussing, I realize there may be some hard copies, those are the ones with 10 centimeters of dust on them, those would be the hard copies. As I showed you before, it may be a four-inch, five-inch stack. The other ones, as you know, is a box or two full of documents.

MR. THOMAS: The production that I -- that Butler Snow received is

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a box or two of documents.
MR. ANDERSON: Right.
MR. THOMAS: More than three Red Wells for both Klosterhalfen and Klinge.
MR. ANDERSON: Probably, yeah.
MR. THOMAS: Were any of the documents produced on disk?
MR. ANDERSON: To you.
MR. THOMAS: "To you" meaning Butler Snow or to David?
MR. ANDERSON: Oh, yeah. I don't know because I was here, but I think they were produced in hard copy. That was my understanding they were produced in hard copy. If there was a disk in there, they may have been. I don't know that there was.
MR. THOMAS: There was a disk in there that's a conversation or a discussion at a conference. I have listened enough to that to know. I didn't want to listen to any more of it.

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But I'm just trying to figure out if I have a complete universe of documents that you've collected, and I don't know the answer to that.
MR. ANDERSON: Except for what's coming on Saturday per my earlier discussion on the record, you should have them.
MR. THOMAS: Again, for my benefit and I'm not doing anything other than trying to understand, did you make the production of all of the documents from Professor Klinge and Professor Klosterhalfen at the same time?
MR. ANDERSON: I don't know because I didn't stand there at the mailbox and ship the documents because, as you know, I was here. So I assume that they were roughly the same time.
MR. THOMAS: Okay. I'm becoming concerned I don't have all of the documents is my point.

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MR. ANDERSON: If so, it wouldn't be from our end. It would be on your end. And so all I'm saying is I can't speak to your side. I can just speak to my best belief from our side.
MR. THOMAS: I understand.
MR. ANDERSON: Okay.
MR. THOMAS: I'm not accusing anybody of anything.
MR. ANDERSON: Like you said, I am just trying to understand.
MR. THORNBURGH: Can I maybe add some clarity? There were two productions for Klinge. If you personally only received one box, then another box was sent the following day. So you may -- I don't know what you received from Butler Snow. I know that Butler Snow received two productions.
(Klinge Exhibit 7 marked for identification.)

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QUESTIONS BY MR. THOMAS:
Q. Doctor, I hand you what's been marked as Deposition Exhibit Number 7.
What is Deposition Exhibit Number 7?
A. This --
MR. ANDERSON: Why don't you look through it before you answer.
THE WITNESS: This is a draft of a first contract between Ethicon and the university and partners at the university were the surgical department and the Institute for Pathology. They had was Professor Mittermayer and for surgery was Professor Schumpelick and the guy responsible from Ethicon was Dr. Hoepffner.
Q. Do you know the date of that agreement?
A. '95, '96, around this. And there was identified some issues to work about it.
Q. Do you understand that to be at

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least a version, a draft, of the contract that the parties ultimately executed back in around 1995 to provide for the Ethicon support of activities at the university?

A. Please, can you --

Q. Do you have a final version of the contract?

A. I don't recall any detail there, but I have no doubts that I have seen and there is a final version of this contract. There has been this -- there was this contract between the university and Ethicon in this form.

Q. Did you have anything to do with the negotiation of that contract? Did you comment on the draft?

A. The -- all what is related to the content here, to the scientific content or the content, what we should work on, that is a commented, corrected, changed by me as well. So I saw all of these drafts and then give my comments, then they were changed, then finally they got to the legal department and they checked it again and then they were

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signed by the people there.

Q. Okay. And who did you give your comments to?

A. This, of course, will be a conversation between Dr. Hoepffner and me. We sent it directly.

Q. Okay. Did you go through Dr. -- Professor Schumpelick?

A. If there's any question, we discussed it at our department or with Professor Klosterhalfen. At that time, Professor Klosterhalfen, we discussed it before so there was a discussion among all of these peoples at the university and then the partner was Dr. Hoepffner there.

Q. Were you the person on behalf of the university who negotiated the terms of the ultimate agreement, which is Exhibit 7?

A. So negotiate means that I'm the only person who changed something? No.

Q. No.

Were you the person who had the responsibility from the university to discuss with Ethicon changes the university wanted in

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the agreement?

A. If such a draft turns ten times around, the first eight versions are going to me.

Q. Okay. And my point is there were a number of people at the university that had something to say about what went into the contract.

Is that fair?

A. As the legal officers, they have some specific things they have to add there, yeah.

Q. And Professor Mittermayer may have specific things, Professor Schumpelick may have specific things?

A. But I cannot recall any specific changes of these two to this --

Q. That's not my point.

My point is whatever comments anybody had from the university were passed to you so you could pass them on to Ethicon?

A. It was my responsibility at that time to make it pass.

Q. Very good.

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A. To send it and receive it so.

Q. And the person that you dealt with at Ethicon is --

A. Dr. Hoepffner at that time. But it changed, but at that time, it was Dr. Hoepffner.

Q. Okay. And I believe you said there were several drafts that were traded back and forth?

A. Yeah, usually.

Q. How was it that you happened to be the lucky person to be in charge of the contract?

MR. ANDERSON: Objection to form.

Go ahead.

THE WITNESS: First of all, because I'm clever enough to do so and the other people thought that I'm clever enough to do so. It is a -- to understand it completely, you have to go back in the history when this collaboration and when this idea started and, therefore, I was the man

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responsible for development of meshes, to study, to make surgical research in this field. That was my profession and, therefore, it --

Q. Doctor, I believe you testified in your last deposition that Ethicon hired FEG to develop VYPRO I.

Is that true? Did I read that correctly?

MR. ANDERSON: Objection. Mischaracterizes.

Explain it.

THE WITNESS: So, again, in 1994, when it became clear that we had a development project or we had a project to develop meshes with Ethicon, we mainly discussed it with Dr. Hyntsch. And we come together and it was clear that we need someone who provides us with textile constructions and so we had to decide -- the idea was quite simple. We wanted to reduce the material. We wanted to adopt it to the physiological requirements and,

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therefore, we want to change the textile characteristics.

But to include all of the options, we need a textile engineer in doing this. At that time, it was not available at Hamburg Norderstedt. They didn't have a textile engineering facility there. Therefore, we had to look some -- to places there.

The idea was born in strong -- in collaboration with Boris Obolensky who at that time was at the Institute for Textile Engineering at the university. So he was very well-informed about the -- that there is an option there. At that time, it was in 1994 there -- the FEG was very small. They didn't deal with medical devices and Obolensky was at the Institute for Textile Engineering, and at that time -- so we planned and organized this project to develop the mesh and I had several discussions with Dr. Hyntsch there.

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So, first of all, we tested all current materials, we developed some methods to evaluate what happens to these meshes and then the point came that we have to decide where and how to make these new mesh constructions, this modified mesh constructions. And there has been two options; the first is you have to go -- you can go to the technical university. It is -- it is very famous. It is an official site, maybe a little bit more long-lasting and the other alternative was a factory in Kemnitz in the former GDR and in 1994, it was empty. So it was a factory without having to do a lot of things.

So this has been the two options to realize a modified mesh material either in Aachen or either in Kemnitz. And I went with Dr. Hyntsch to Kemnitz and we visited the factory and talked to the people there. In a car, we went there. And afterwards it

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was clear we need a decision. Either Kemnitz or Aachen and then Ethicon and I assume Dr. Hyntsch, he decided, no, we want to have the power of the technical university. We want to have it in Aachen and not in Kemnitz. And, therefore, we tried to realize it.

Meanwhile Boris Obolensky left the university and went to the FEG Textiltechnik. And, therefore, there was a contract, I've never seen this contract, but there has been this linkage of Ethicon. They hired the FEG Textiltechnik to make this modification of the mesh materials and the FEG, Boris Obolensky, he found the manufacturer in Goth where later on VYPRO and ULTRAPRO™ is really manufactured.

So, yes, they hired the FEG to make the VYPRO.

QUESTIONS BY MR. THOMAS:

Q. Okay. When Boris Obolensky was at the textile institute at the university,

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did you collaborate with him in the development of VYPRO mesh?

A. First of all, the idea was raised in a discussion with Boris Obolensky in 1993. He was the person who told me that there are several textile options to optimize this mesh and that the current meshes at that time are not very satisfying from his point of textile engineer. So that raises the idea that you can do something with it.

Later on, it was a collaboration with him that we got the textile characteristic of meshes at the Institute for Textile Engineering. It was done independently of this institute. Later on, he made the modifications for Ethicon and since then, when we need some modification of textiles, either for -- in the project for VYPRO or later on for the research institute when we have some other grants, we always did it in collaboration with the FEG. So we have this -- yeah, this ivitäten, research activities in parallel and we need a lot of textile modifications. And Ethicon at that

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time was not able to provide this.

Q. What was Professor Obolensky's title with the Textile Institute?

What position did he hold?

A. Dr. Obolensky.

Q. I am sorry.

A. In the textile sciences is something special.

He has been what is called here overassistant. That is the -- you have the head of the institute and then you have two, three persons on the level below.

Q. So is it fair to understand that he, Dr. Obolensky, is the first person who approached you with the idea of changing mesh design to make a larger pore, lighter-weight mesh?

A. The starting point of all of this mesh trouble has been a -- has been a private session at my house. There has been 20 women in Aachen in the beginning of the '90s, '91, '92, they founded the center for mothers to take care of children and so on, and these mothers are coming together and

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some of these founders have been my wife. And in 1993, in December, I had the invitation -- I had the -- I had the order from Professor Schumpelick to prepare a preparation of meshes in the Suvretta conference in 1994 in St. Moritz.

In December of 1993, we have a pre-Christmas meeting there of the women of this mother center there. And you can imagine a lot of children, some husbands there, sitting around and all of the wives chattering and chattering, and then you have to talk to the husbands there. You don't know each other and then it was the first time that I managed or that I noticed that there is someone as a textile engineer. I didn't know about it.

And in preparation of my presentation for the Suvretta, I always have a piece of mesh in my pocket and, therefore, we have been sitting there and I showed him the Marlex mesh, he said, "Well, I wouldn't made a sock out of it. It is so strong you can wrap in a cup." And then we start to

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talk about it. And then I said okay, I have to make a presentation, and I would like to send him some of these ideas and experiences. And then it comes back what for them is a very simple approach to textile things.

But I learned from this hosiery is that there are -- what textile tests can be done and so on. But this was the starting point that he said, "It is too strong. Do you know how strong it has to be?" That was the question at that time point, and then I looked to the literature without Google. You have to go down to the bib and look to all this all stuff and trying to figure out what is the stability you need. That was the starting point, and it was first documentation of this effort was in the first Suvretta book.

Q. When did Dr. Obolensky leave the university?

A. In 1994, sometime.

Q. Was the FEG already in existence at the time he left?

A. Yes.

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Q. And what was the business of the FEG before he arrived?
A. It was engineering of machines. Mainly a quality control of -- when you manufacture paper, for example, you have some fleece to press the water off, and this fleece is somehow a mesh form and they wanted handful of engineers. They optimized these machines. They found some or elaborated some technical solutions for technical problems for airplanes, cars and for these printing or paper manufacturers mainly which are related with textiles.
Q. And at some point, Dr. Obolensky became one of the owners of the company, correct?
A. Yes. Mainly -- yeah, but I don't know exactly at what time point, but --
Q. And who was --
A. -- he's one of the two or three people that are the owners of this company.
Q. And who are the other owners of the company?
A. Stefan Schneemelcher is the

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name.
Q. And does he have an active responsibility in the management or operation of the company?
A. They both have it, yeah.
Q. What does Stefan do?
A. He's an engineer as well. Both are coming from the Institute for Textile Engineering so they are both engineers. I don't know exactly -- I know that both have some projects that both have some devices, but they have different responsibility. One is for safety regulations more or less focused or for contract, but it's close together. It changes all the time, and I'm not familiar with the details.
Q. Do you know how FEG was compensated by Ethicon for the work that it did on the VYPRO mesh?
A. I have heard somehow where a figure, but I've never seen a contract.
Q. What have you heard?
A. I've heard it was about 100,000, but I even don't know whether it's

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Deutsche mark or Euro. It has to be Deutsche mark at that time.
Q. Okay. Do you know whether FEG had any royalty interest in VYPRO?
A. I've heard that it was a fix sum without any subsequent requirements or demands or royalties or obligations. It was just for this -- at that time, it was not in the interest of the company to be there.
Q. Did FEG have any responsibility for VYPRO II?
A. No. I don't know any, no.
Q. Are you aware of any responsibility that FEG had for any mesh manufactured by -- strike that.
Are you aware of any interest that FEG had in any mesh sold by Ethicon other than VYPRO I?
A. They don't have -- even have an interest in VYPRO I. So they --
Q. Okay.
A. So they made it, they know how to made it, they know all of the story, they are included in the story, and that's -- and

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then the collaboration stopped. We tried to put them together and there was a meeting from these guys in Hamburg in May 2000, 2001, where they met with Dr. Engel to see whether this can be continued, but I was not participant of this meeting.
Q. In May 2000 or 2001, when FEG met with Dr. Engel, what was the purpose of that meeting?
A. The purpose of this meeting was that we have been -- that we did show that the VYPRO was a very good, a very successful approach to improve -- to develop new meshes by the use of science of the university, textile engineering and a manufacturer. And then we have some subsequent research projects funded by the university that we wanted to work on the PVDF at that time. So one option would be is that it is separated again and we have our research project with the university and the FEG to work on PVDF.
A better way would have been to put -- to keep this together and to work together. But then there has to be an

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agreement between the two companies.
Q. The two companies being Ethicon and FEG?
A. Yes, obviously.
Otherwise, we -- and everyone knows it -- we have this scientific project with PVDF from the university working with the FEG and they're providing us the material. They know how to manage, it and they're providing us the mesh structures and on the other hand, we have this history and this collaboration with Ethicon. For us, not a very happy situation. So the best would have been if they really keep to work together.
Q. And was the goal of the meeting to have FEG and Ethicon work together to develop a PVDF mesh?
A. This was -- not restricted to PVDF. Our hope was that they come together, work together and that we can continue to talk to Obolensky and Ethicon and all -- making all of this together and, therefore, we told Dr. Engel that they have to consider

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that Obolensky knows how to do a mesh. So to keep this knowledge to the company for the future, it should be wise to keep him.
Q. And --
A. And that was the reason that we said to both meet, meet and try to continue your collaboration, but the result was not successful.
Q. You said "we" a number of times.
Who tried to put the meeting together, you and who else?
A. Bernd Klosterhalfen.
Q. Was Professor Schumpelick involved at all?
A. No.
Q. Okay. And who did you speak to at Ethicon in an effort to arrange the meeting with Dr. Obolensky?
A. It was a meeting -- I remember at least -- we have several meetings, and we have several times discuss all this continuation, future prospective and so on, it's always a topic, but this was a meeting

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in Hamburg Norderstedt in the office of Dr. Engel where I remember quite clearly that Bernd Klosterhalfen and me were sitting there with Dr. Engel, and then we told him that it should be necessary to meet for them and to combine their capabilities.
Q. What did Dr. Engel say when you made that proposal?
A. Obviously, he agreed to make this meeting.
Q. Okay. Did you attend the meeting between Dr. Obolensky and Dr. Engel?
A. No.
Q. Did Dr. Obolensky report to you the results of the meeting?
A. He roughly gave me his impression that there has been different expectations. The problem for the FEG -- the main problem for the FEG was that they have been afraid when they have good ideas of good mesh, that there is not obligatory push that this mesh will be manufactured and will provide some royalties for the FEG company, and there was not agreement -- no agreement

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that Ethicon agreed that they -- they agreed that they always -- will not always, but usually will realize the products that are provided by the FEG. And that means that it can be that you have a inferior product and this is sold and the good idea is keeping down and this would be in agreement with the contract.
So to overcome this problem, it would be necessary to find a participation, even at the products that already are on the market and on the future prospective.
So this is the conflict that was not solved in this.
Q. I think I understood that. Let me see if I can break it down a little bit.
Is it fair to understand that FEG wanted some assurance from Ethicon that Ethicon would market the meshes that FEG brought to Ethicon?
MR. ANDERSON: Did you say would or wouldn't?
MR. THOMAS: Would market.
THE WITNESS: Yes, or at least

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have some -- they need some -- some -- some confident thing where they can rely on for the future, yeah.

QUESTIONS BY MR. THOMAS:

Q. Okay. Did you ever speak -- strike that.

Did you understand that to be the big breakdown in the negotiations that Ethicon couldn't provide FEG any assurance that they would market the meshes that FEG brought to Ethicon?

A. No. No, definitely not. It is rather an expression of the attitude, how you think to work in future or how to manufacture, how to develop. Obviously, the Ethicon people at that time they believed they have employed young textile engineers. They have bought some machines there. They thought they could do it themselves without any help, and they don't care what happens outside. At the FEG in 2001, 2002, they haven't been on the market at that time, but they -- obviously, they don't have the vision of what happens in the future.

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Q. Did you ever talk to Dr. Engel about the meeting?

A. I don't recall.

Q. Is the only person that you've spoken to about the meeting who was present was Dr. Obolensky?

A. I -- I assume. He just reported me --

Q. Okay.

A. -- his impression.

Q. Okay.

A. So I don't have anything more.

Q. Was the meeting with Dr. Engel before or after the letter that you and Professor Klosterhalfen wrote to Dr. Engel about VYPRO II?

A. I guess it was after, but --

Q. Okay.

A. It's 2000, 2001.

Q. Your best judgment or your best recollection is that the meeting with the FEG, with Dr. Engel, was after the time that you and Professor Klosterhalfen sent the letter to Dr. Engel about problems with VYPRO II?

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A. Or maybe same year and May, the meeting was and in June, the letter was. So maybe something.

Q. Okay. To your knowledge, after that meeting with Dr. Engel at FEG, were there any further discussions between Ethicon and FEG about a collaboration?

A. I know that there has been some discussions on some conferences between Boris Batke and Dr. Obolensky, but I don't know any further details. Only that they have contacted each other, not a collaboration.

Q. Do you have any idea whether the relationship between the companies is pleasant and cordial?

A. I don't know the -- I didn't get the last word.

Q. Cordial, they get along together.

Let me start again.

Do you know from your experience whether the relationship between FEG and Ethicon is smooth?

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A. Smooth.

Q. Is the relationship between FEG and Ethicon bad?

A. So, first of all, they are all professionals. I assume they're all professionals and they have their different standpoints. It is from the market share, you have an elephant and you have a fly. The fly is the FEG. It has good ideas, good products, but it's a very small one and you have the giant there. So this relationship is like it is.

Q. Okay.

A. And there is only one legal conflict and this is a conflict I don't know any details, but maybe you have in all of these thousands, hundred thousands of documents, the details. There is a legal conflict dealing with the PVDF patent. They're -- you know, the Ethicon -- and I just saw it one year or two years ago. Ethicon has a PVDF patent made in 2002. And this is obviously in conflict to the PVDF patent of the FEG. I don't know which one is

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first, which one claims all what has been done, but there has been a legal -- legally -- there has been a conflict between the two companies and they have been at the European patent justice or court in Den Haag and in Munich, and they fought a little bit or the lawyers fought a little bit. Mainly the lawyers fought.

Q. Has that dispute been resolved, do you know?

A. I've heard that it's resolved, but mainly there are some subsequent redos and appealings or whatever, yeah.

Q. Did you have any involvement in the patent dispute?

A. I was -- I got the information that it was like this, but I never was present at any of these meetings at the courts. Yeah. I'm on the patent of the FEG, but I'm not on the patent from Ethicon so.

Q. Dr. Klinge, we spent some time talking about the relationship that you had with Ethicon and the contracts that are in place.

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Tell me the kinds of projects that you worked on in the '90s for Ethicon, other than VYPRO.

A. Other than VYPRO. Do you mean VYPRO, specifically the development of this mesh or our mesh restructure? I got more than 20 different mesh materials from Ethicon that we tested it, that we evaluated under different conditions.

Q. I'm keeping VYPRO separate from your other research.

A. You're keeping mesh out?

Q. So what I want to know is exactly what you just described, the 20 different mesh materials that you received from Ethicon.

A. Yeah.

Q. Did you receive 20 different mesh materials at one time or over time?

A. I cannot separate it from the development of VYPRO because the VYPRO was the aim, the purpose, we did. We started -- we had to learn -- in 1994, we had to learn everything about meshes. There hasn't been

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any investigation and any good literature about it. So we have to start with the textile characteristic. First time that we provided these testing of mesh materials at a Textile Institute. And we wanted to know what happens to the tissue, what happens to the function when we need -- when we implant some meshes. We need some mouse models, rat models. We have to look what is appropriate, what is the better thing. And then we started with the first current meshes to learn how to correct the rise of this tissue response. Then the next was first modification of these meshes. Define a range of the stability of the mesh materials, the polymer, we have to define whether it's polyester or polypropylene. Then we created in a small period of time the modifications A and B that later on become the VYPRO mesh.

Again, four modifications that has been tested. The next question was impact of Vicryl on it. So we made some modifications coated with Vicryl. We left the Vicryl out and compared the reaction.

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All of this is published in our subsequent literature.

So the steps has been there that we have regular meetings, that we proposed -- we identified some questions, that I made some proposals how to make this and then we're sitting together and it was clear we need -- when we wanted to investigate the impact of Vicryl, we wanted to have three, four different mesh materials, modifications with various parts of Vicryl and then we proposed this to Ethicon and then they -- people said, "Okay, yes, what do you need?" And then we say, "We need 2.5 to 3.5-centimeter meshes with this characteristics. We need them best in May that we can start in June." Then they said, "No, it's not possible." One month later, "Yeah, okay."

Then we started one month later. Then we got a box with these mesh modifications, and we got the suture material as well and all of this together then was used for the experiment.

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When we are all finished with this, the next question was, for example, sometimes a mesh quite similar to the soft Prolene® mesh were coming and they were interested in -- so the impact of various polypropylene amount to compare this or to compare -- then we had a -- wanted to investigate whether nuclear medicine can help us. We made a pet study, and then again, we have to decide which mesh material and what model we want to have and this was done in discussions with Ethicon, and if we need some material, we got it from -- they prepared the material for that.

Q. Okay.

MR. ANDERSON: Did you say pet?

THE WITNESS: Pet, p-e-t, nuclear medicine where you can see the inflammation.

QUESTIONS BY MR. THOMAS:

Q. I'm going to break that down a little bit. That was a very helpful explanation. I want to explore some of the details of it.

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You said you had regular meetings.

Who was part of your team that was responsible for understanding these 20 different meshes?

A. Who was part of your team responsible for understanding? Me.

Q. So did you have people help you or did you just --

A. A lot of people. So the issue was there that you have to address all these various problems. We really looked to all sides that may be a concern. We go to the microbiology, to all of these. It is impossible to take care yourself of all of these things.

Q. Exactly.

A. Therefore, I'm running around and asking my younger colleagues if you want to make research, I can offer you a project, it is paid, you get the material, you have to do the operations, you have to do the evaluation, and we will publish it. Are you interested in doing so? Yeah, and most of my

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colleagues are interested in doing so, and if you look to the references of my publications, you see that almost everyone or two-thirds of the department sometimes belong to some of these projects and took part of this.

Q. Was there a core group of people within the Aachen group as it's been described that you worked with through the '90s with Ethicon?

A. There is no structured core group. It is -- I am -- I'm the core group there, and there is a changing amount of people for the time they are doing surgery, they're in the hospital, they made it, then they left it. So the -- the main continuation that is my person.

Q. Is it fair to understand that you use younger people who were spending their time at the university learning to assist you in research projects that you might publish with them?

A. I would object to the term "use" because use is in my -- what I learned

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from -- when we use the word "use," it has a negative feeling thereby.

Q. Not intended at all.

A. I offered them the opportunity to work with this project, and they agreed to it.

Q. Let me ask you this.

Is it fair to understand that you collaborated with the younger people who were being taught at the university in order to conduct the research and writing necessary to further the research you were doing?

A. If you put all people together working in this scientific field with all of the various aspects, maybe 50 to 100 persons, that at some parts contributed, collaborated with me.

Q. Dr. Klosterhalfen was a constant throughout the whole process, wasn't he?

A. Almost always.

Q. Okay.

A. At some time period. There was some significant research where he was not

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part, but in the first years when he was in the hospital, he was, of course -- we almost always took the chance to have him get a look to what we say.

Q. Okay.

A. But when he left the university, he -- this was less.

Q. Well, he left the university in 2003?

A. Three.

Q. And so from '94 to 2003, Dr. Klosterhalfen was a significant part of your efforts?

A. Yes, without any doubt.

Q. Was there anyone else on the scale of Dr. Klosterhalfen who contributed to your efforts in understanding mesh?

MR. ANDERSON: Objection.

THE WITNESS: Nothing that can compare to the contributions of Dr. Klosterhalfen.

QUESTIONS BY MR. THOMAS:

Q. Okay. What role or responsibility did Professor Schumpelick have

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in your research?

A. His responsibility, he brought the focus hernia to the university, which is not very popular. Most of the universities are focused on cancer research, but he was interested from his story to hernia and, therefore, he encouraged and let and was happy to have research on this hernia issue.

As a head, he was the only person who can sign these contracts. He has to sign every contract. Every research contract. So he was responsible for this. He attended hundred thousands of conferences dealing with hernia, dealing with meshes and have countless presentations there. And for five to ten years, he got most of the slides from me. So he agreed to this. We discussed -- when I offered him the slides, we discussed the presentation and, yeah, he agreed with this. We have a discussion about the -- all these results and he presented it to the international audience, and he has to withstand the discussions about cancer, about all this what has been discussed.

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Q. It's fair to understand that Dr. Klosterhalfen was the person who was able to give you the opportunity to do the research that you did? Is that fair?

MR. ANDERSON: Did you say Dr. Klosterhalfen?

QUESTIONS BY MR. THOMAS:

Q. Yeah, bad question.

Is it fair to understand that Dr. Schumpelick is the person who is responsible for giving you the opportunity to conduct the research that you did?

A. We thought a lot about how to find the best phrase for it. I would prefer to say he was able to hinder it. He could have been able to have it stopped. He could prevent any research in this field. He didn't stop us. He was not able to stop us in our activities.

Q. Okay. But he --

A. But he -- but I would not agree that he really supports our research. He uses it. He didn't stop it, but support I -- I have some problems with it.

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Q. Okay. During the time that you were collaborating with Ethicon through the '90s up until 2000, you mentioned the experiments that you would conduct and that you would request materials from Ethicon.

Was Ethicon the sole source of the meshes that you tested?

A. Mostly. Ethicon provided, of course, the test -- or the projects we did with Ethicon. We have other projects, as I've told, for example, PVDF development where we need PVDF modifications that we got from the FEG. And we took some or we made some experiment with the Parietex where we wanted to see what happens to polyester multifilament, and there I asked Sofradim at that time if they wanted to supply us Parietex and, therefore, we got this material from Sofradim. Some other materials we took from our OR, from the clinics.

Q. Before our break for lunch, I want to ask you something before I forget.

Several minutes ago you made a comment about Dr. Barbolt coming to Germany.

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A. Uh-huh.
Q. When did that happen?
A. Frequently times we figure it out and I usually forget it. 1999 or 2000.
We prepared a summary of all activities in English language at that time because it was announced that two American guys and one was Barbolt, that they visit our group in Aachen and we prepared some presentations there and we were quite -- we were somehow exciting to have -- to start in this discussion with the US experts. Because in the time before we have this agreement with the German guys, no problem with it, but this was the first time that they were coming, and I remember that Klosterhalfen presented his results as he did it today and the reaction from Barbolt just was it's not relevant. That was it.
Q. Was the meeting in 1999, 2000 your first contact with anyone from Ethicon from the United States?
A. I'm not sure. There has been one or two other meetings where I was invited

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one of these confidential drafts. Maybe, maybe in this field where I've been in Hamburg Norderstedt, I was invited with Bernd Klosterhalfen to present our findings and there have been two other guys in another room where we discussed it, yeah, but I don't know the name or --
Q. Do you know who was traveling with Dr. Barbolt?
A. I don't recall.
Q. You said there were two.
A. I don't recall, and I didn't find the protocol of this meeting.
Q. When you say "the protocol," the description or the minutes of the meeting?
A. I know that the Ethicon guys usually made some minutes of this meeting and some of them I got, but I didn't find any further documents showing any details.
Q. You said a minute ago that in anticipation of the meeting that your group prepared a summary of all activities.
A. Up to then, including the

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animal experiments, including the publications and some proposals for further ongoing activities.
Q. Was that in English or German?
A. It's in English.
Q. Who was responsible for preparing that document?
A. I did it. I got the order from Professor Schumpelick to make such a thing, and then I started to write it and collect it and design it.
Q. How long was it?
A. 20 pages.
Q. Do you still have a copy of it?
A. You have it already in the pile of paper.
Q. Okay. Does the 20-page presentation contain a list of attendees, people who were there?
A. No.
Q. Who was there from the Aachen group?
A. I only remember Schumpelick, of course, it's me, it's Klosterhalfen, but I

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don't recall there has been a -- or the number of participants changes according to whether they left the department at that time or whether they're on duty or in the OR.
I even do not recall whether it's Dr. Hoepffner or Dr. Engel, but some of these.
Q. How long did the meeting last?
A. Two to three hours.
Q. And you made a presentation?
A. I don't recall precisely what I presented there, but I assume that I made the presentation as Bernd Klosterhalfen and --
Q. And did --
A. Usually we prepared several presentations there.
Q. And Dr. Schumpelick, did he make a presentation?
A. Usually not.
Q. And what did you understand the purpose of the meeting to be?
A. I didn't have any information why at that time, whether there -- what intention is by Ethicon there. We were happy

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that we have got the opportunity to have a discussion with another continent these ideas. It was as our usual meetings that we discussed the current stages, what is going on in the future, what can be done, how we can help support, what has to be done there.

Q. What was the context of Dr. Barbolt's comment about Professor Klosterhalfen's work?

A. What was?

Q. What was the context? How did it come up? How did Dr. -- strike that.

How did Dr. Barbolt happen to comment on Professor Klosterhalfen's presentation?

A. How he come to this conclusion, I don't --

Q. Let me ask it another way.

What was the nature of the presentation from Professor Klosterhalfen on which Dr. Barbolt commented?

A. The presentation of Bernd is always that the larger the pores the better. The smaller the pores it means intense

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inflammation and fibrosis, and this is relevant and, therefore, we develop the VYPRO mesh and material changes the reaction of the tissue by some markers, expressed by some markers, by some staining and so on. That is what he since then -- always is telling, finding and what we are convinced is confirmed by all of these data. But obviously, he has the opinion that material doesn't matter and meanwhile I know --

MR. ANDERSON: "He" being Barbolt?

THE WITNESS: Barbolt.

MR. ANDERSON: Go ahead, I am sorry.

THE WITNESS: And meanwhile I have learned that he think that everything is mild to moderate and didn't see any differences or any impact of the material and disappointing point for us was that we -- we would have accepted very well a discussion to see what are the methods, what can be done better and

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so on, but a summarizing statement is not relevant. That is a killer not only for the future, but for any communication and, therefore, I -- we went out and were a little bit, yeah, disappointed about it.

QUESTIONS BY MR. THOMPSON:

Q. What exactly did Dr. Barbolt say?

A. Precisely, I didn't make any writing there. But in the context, it is not relevant.

Q. Okay. And meaning that Dr. Klosterhalfen's work was not relevant?

A. Yes. Because he was -- he was announced the pathology of -- from Ethicon from the US, the man who is experienced.

Q. Now, you said that you learned later that everything is mild to moderate?

A. Yeah.

MR. ANDERSON: No --

MR. THOMAS: I'll ask him.

THE WITNESS: Okay.

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QUESTIONS BY MR. THOMAS:

Q. Who did you learn that from?

A. I didn't learn that this is right. I learned from the documents that in some of the documents of Barbolt from his study, he compared different mesh materials, heavy-weight, light-weight and all thing, and his findings were it is similarly mild to moderate.

So if you made a measurement where you don't find any differences, I think your parameters are too rough or your eyes are too closed to find these differences. But if you believe that it is everything similar mild to moderate, it is -- yes, it is -- meanwhile, I know that may be the reason that Barbolt come up to this opinion, but I'm not an expert of Barbolt.

Q. So have you reviewed studies conducted by Dr. Barbolt to understand his opinions in that regard?

A. I've seen some of these documents, and in some of these, I think a deposition of Barbolt, but yeah, I've seen

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the data of his report and his publication, I think, where he compared different mesh materials and the result was mild to moderate. He very often repeated that his reaction is mild to moderate. So it's a very often used phrase by us.

Q. And, Dr. Klinge, is the information that you've described about what you've learned about Dr. Barbolt only come to you during your work on this litigation?

A. I don't have any other information about the work of him.

Q. Okay.

A. Just this mainly based on this personal impression at that time, which was rather disappointing and it was really no scientific discussion and later on, I've seen his comment, his interpretation of his data.

Q. Okay.

A. These are the two only --

Q. At the time of the meeting in 1999 or 2000, you didn't have any idea of the basis of the comment that Dr. Barbolt made at the time of that meeting; is that fair?

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A. I didn't -- I didn't know -- we just got this reflection by him and then it stopped. There was no opportunity to discuss these data as we did it now.

Q. It was only the last three years during the source of this litigation that you understand how Dr. Barbolt has analyzed certain data from studies he conducted that you draw this conclusion?

A. During my work and I'm looking very carefully to all of the references and literature and science about meshes, there is no need to focus, to think about this study. I never had the -- I never saw the necessity to think about it. Just only because I'm asked in -- at the opportunity of this litigation, I had to look to these data there.

Q. And that's the first time you drew a conclusion of what Barbolt meant when he said it wasn't relevant; is that fair?

A. I didn't get the -- all correction.

Q. And that's the first time when

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you reviewed the depositions and testimony of Dr. Barbolt in this litigation that you drew a conclusion of what Barbolt meant in 1999 when he said that Dr. Klosterhalfen's data was not relevant; is that fair?

A. It is my assumption that maybe he had thought at that time that because of this he gave it to us.

Q. Okay.

MR. THOMAS: Let's take a break for lunch.

THE WITNESS: However, it's a difficult style to do it in this manner.

(Off the record at 12:59 p.m.)

(Klinge Exhibit 8 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, Mr. Anderson has kindly given me a copy of a letter from you and Dr. Klosterhalfen to Dr. Engel that is dated December the 8th, 2000. I've marked it as Exhibit number 8.

Is that the letter to which you

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referred to earlier where you and Dr. Klosterhalfen wrote the letter Dr. Engel advising Dr. Engel of issues with the VYPRO II about which you're concerned?

A. That is true.

Q. I don't need you to read word for word, but as you review the letter, what are the nature of the problems that you've identified with VYPRO II?

A. I think it will be best to -- every sentence has some --

Q. That's fine. Then you do whatever you need to do to explain to me.

A. So based on the results of the -- the fresh results of our experiments in rats with the implanted VYPRO II meshes, we have to consider that these mesh modification biologically behave similarly as a common heavy-weight mesh as reason for the intensified inflammatory fibrotic reaction has to be discussed the considerable amount of polyglactin, Vicryl, with the considerably fibrogenetic power and the use of multifilaments with the enhanced surface

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quality of the material. These results are in accordance to the studies that are done by you and Dr. Holste in pigs.

From our point of view, the VYPRO II, as based on the present data, cannot be considered as improvement of the VYPRO mesh because the amount of the material and the surface is significantly increased and the pore size is reduced. Considering these effects, it is in contradiction to the -- to our published principles that have been the basis for our joint development of the VYPRO mesh. We want to state that we haven't been involved in the development of this specific mesh modification. Even if the name VYPRO II, VYPRO, may indicate that we have been involved. The clinical relevance of these experimental results we cannot -- we cannot evaluate or the significance or relevance of these experimental results; however, we advised a very careful testing.

We advised him to test it very carefully and hope this modification rapidly will be replaced by a large pore material and

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surface reduced monofil modification. Respectfully.

So that is the entire text.

Q. Did Dr. Engel respond to your letter?

A. I don't remember any response.

Q. Did you discuss your letter to Dr. Engel with anyone at Ethicon?

A. With anyone else?

Q. Yes.

A. I don't recall. He was the head of the R&D department at that time.

Q. Did you take any other action with respect to VYPRO II other than writing the letter to Dr. Engel, which is Exhibit 8?

A. No, we didn't. So far I remember correctly, we didn't intensify our warning to VYPRO II.

Q. Okay. Now, back to our work that you were doing from the period 1994 to 2000. You said you had regular meetings with Ethicon personnel.

Did those meetings occur both at Norderstedt and in Aachen?

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A. Yeah. We met in Norderstedt. We met sometimes at the factory where later on the meshes have been produced, we met there. Or we met -- mostly we met in Aachen.

Q. And when you met, were there agenda prepared for the meetings so you knew what you were going to discuss?

A. Usually there had been an agenda that has been spread later on my e-mail to everyone and usually we prepared or I organized that we have some actual presentations of the results of the projects.

Q. So the purpose of the meeting was to keep Ethicon advised of the status of the research that you were doing, correct?

A. The first intention was to give an overview current status of the past projects, of the present projects and of the ongoing projects to say what we need to them. There has been sometimes occasionally some other -- some minutes where they had some devices, 3-D devices where they wanted to present these modifications to the -- that we can feel on it so that we can give some

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comments on this sometimes. Not every time.

Q. Did the same group of people from the Aachen group attend these meetings with Ethicon?

A. There is -- always there's Professor Schumpelick there. Most often I've been there. Professor Klosterhalfen very often and the other people on demand. If this project is presented there, if this was ready to be presented there or if they wanted to start a new project, I tried that these guys or some of this group, I usually wanted to have two guys working in one project. If one is on holiday or sick or so that you have some sort of continuation. But one of these guys is there to discuss this.

Q. Dr. Klinge, you've identified now agenda and presentations and I'm sure there are other documents that came out of those meetings.

Did you save the documents from those meetings?

A. I have some of these agenda, e-mails put on your file there are some.

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Q. Okay.
A. It is very often prepared by Dr. Holste or Dr. Hellhammer. They sent the same or the final draft for the agenda and said how many people, when they come so that we have to arrange the peoples are not in the OR at that time.
Q. Okay. Are they in English or German?
A. In German.
Q. And are there presentations included in the documents you produced as well?
A. We --
Q. Presentations related to the meetings with Ethicon, just so we're clear.
A. There aren't specific presentations that are linked to these working meetings here. Because every one of my colleagues just showed three, four, five slides there. No big presentations. I added to your -- to the files several presentations I made in connection to the Ethicon activities.

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Q. Is this before the year 2000 or after 2000?
MR. ANDERSON: Both.
QUESTIONS BY MR. THOMAS:
Q. Okay. You mentioned your review of the Barbolt animal studies a few moments ago that you reviewed in connection with the litigation.
In your -- what animal studies did you review of Dr. Barbolt, do you remember?
A. It's mainly in -- I remember there has been a famous dog study and some rat studies 90 days or something around this.
Q. Have you ever tried to replicate the studies conducted by Dr. Barbolt that you reviewed?
MR. ANDERSON: Objection.
THE WITNESS: In principle, we didn't anything else.
QUESTIONS BY MR. THOMAS:
Q. I'm sorry, I don't understand your answer.
A. Dr. Barbolt in his study with

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the rats, he compared the tissue reaction to various mesh materials and look what happens there.
Q. Okay.
A. We did it since 1994. We are looking to the tissue response to various mesh materials. He saw -- he described that there's no significant difference between these materials. We use the similar materials in our experiments and we had a lot of publications, a lot of findings showing that there is some difference and this is the basis of our work, our scientific work, our opinions in the development of the light-weight meshes, the large pore meshes, the conception.
So, yeah, we didn't anything else --
Q. Is it fair to say that based upon the studies you had already done, you disagreed with the findings of Dr. Barbolt in his study?
A. They are in conflict. They are directly in conflict. His conclusions are

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directly in conflict to our statements.
Q. Is there anything about the study design of the Barbolt rat studies that you can point to that would be a reason for the conflict?
MR. ANDERSON: Well, objection, Counsel. Barbolt rat studies, which ones? Do you have something for him to look at?
MR. THOMAS: No, I don't.
MR. ANDERSON: Because asking him to do that without looking at a study I think is unfair.
QUESTIONS BY MR. THOMAS:
Q. Well, you mentioned a 90-day rat study that you looked at.
Is that right?
A. Yes. I mentioned it, yeah.
Q. Okay. And you recall of that study that Dr. Barbolt compared a number of different meshes for tissue reaction, correct?
A. Yes.
Q. And when you reviewed that

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study by Dr. Barbolt, 90-day rat study comparing different meshes and their tissue reaction, did you look at the study design?

A. Yes, I looked to the study detail.

Q. Is there anything about the study design that you could point to explain the difference in the results that were found?

MR. ANDERSON: Again, same objection, without having -- to put a study -- to ask him about a study without putting it in front of him, I think, is unfair, Counsel.

MR. THOMAS: If he can answer, he can. If he can't, he can't.

THE WITNESS: I can give you a general comment on this.

QUESTIONS BY MR. THOMAS:

Q. Okay.

A. There are his study, but there are several other study or studies as well comparing, for example, heavy-weight more pore meshes and large pore meshes. And it

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depends from the readout whether you find a different tissue reaction, yes or not.

If you don't find a significant difference and come up to the conclusion that there is no different reaction between the Marlex Prolene® and all of these guys and the other guys, if you come to the conclusion that there is no difference, it can have two reasons; first, there is no impact of the material or the readout is not sensitive enough to see any difference there. That only can be the reason for this.

Q. Okay.

A. So we have worked a lot and this was mainly done with Bernd Klosterhalfen together to define readouts to identify these differences. Because from our clinical experiences, we know that there are these differences. We wanted to understand what are these differences and, therefore, we developed parameters that are able to see the impact of mesh material and the tissue response.

So Barbolt when -- or when you

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are coming to the conclusion that there is no impact, the first explanation is that your readout is not sensitive enough.

Q. Okay.

A. Because if you just looking to the weather outside, you will not find any impact from the material on the tissue reaction because you are looking with a insensitive view to this.

Q. You said that you and Dr. Klosterhalfen developed special parameters to measure the tissue reaction to mesh materials.

Is that something that you've published, those parameters?

A. That is -- that is one of the -- this is the first main challenge for us. When we looked at the literature at the beginning of the '90s, there are only a few studies by Hinoul and some others looking to the tissue reaction to mesh materials. There has been only a very rough description that there is some scar, nothing else, and they didn't differentiate between the different

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materials, the different properties. There even was a sufficient characteristic of these mesh designs.

So when we started to think about how to optimize, how to evaluate the impact of a modification on the tissue response, we need to get very precise parameters, reproducible parameters, objective parameters, that helps to find the differences and that helps to understand the differences we know from the OR and we started from a surgical problem and used science to explain the surgical problem, not otherwise around.

Q. So you developed --

A. We developed parameters.

Q. New parameters.

Have you published those parameters?

A. Of course, it is published in -- if you look to our publications in the '90s and later on, we usually introduced a textile analysis for characterization of the mesh material and then we added a very

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precise description of material and methods. We presented the measurement, the quantitative measurement of the partial volume of connective tissue, inflammatory, we counted the cells. So that is all what you have seen in the presentation of Professor Klosterhalfen.

Q. Okay. Other than yourself and Dr. Klosterhalfen, who else studies in this field that you respect?

MR. ANDERSON: Objection as to "this field."

THE WITNESS: I respect very much -- very many persons studying in this field. Most of them have very limited resources to do research in this field; however, they struggle a lot, sometimes they have good ideas so a lot of persons that made presentations at the hernia conferences or they -- all of the people they -- that we could invite at the Suvretta meetings, I have deep respect for their contribution to this

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field.

QUESTIONS BY MR. THOMAS:

Q. Anyone from the United States?

A. There are a lot of -- Matthews from New York, so just the recent ones that I can remember Filippo, Fitzgibbons.

Q. Heniford?

A. Heniford, Kopf, Ransho. Ransho did an excellent job when he developed his institute and made these analysis. Carla Deacon, she presented a lot of textile data to ease the characterization, their amitus clinician, yeah.

Q. Doctor --

A. Great people.

Q. Good.

In the field today, the people you've just described who were involved in research in materials and mesh, do they use the same objective parameters and reproducible tests that you and Dr. Klosterhalfen use?

MR. ANDERSON: Objection.

THE WITNESS: If you look to

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the literature there and if you're trying to identify what is the result of our activities to the present publications, in the presentations, in the publications of Heniford, you will find a lot of our ideas. In the presentations of Carla Deacon, you find a lot of ideas and calculations. If you look to the studies of, for example, Luenski from US, from Bellan from Spain, you find a lot of these ideas. They are looking to the macrophages, they're looking to the fibrotic tissue. They're mentioning pore size, they're mentioning light-weight, heavy-weight. So a lot of these ideas are -- meanwhile became an essential. If you want to study meshes, textiles in surgery, yeah, you will do it in this way.

Q. Okay.

A. And this was not known in the days before.

Q. In the time that you and your

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group were conducting the testing that you did on the 20 meshes from 1994 to 2000 in order to understand the meshes, were you the person who supervised the testing?

A. I don't know what is your meaning of "supervising." I was -- in fact, those -- I was responsible for all these things and I did a lot of these things myself, but there have been some others where my colleagues did it theirselves or themselves without sitting aside and doing it all myself.

Q. So you did --

A. Supervising is maybe the correct term.

Q. Throughout this period, you did animal implantation studies to understand how mesh would interact with an animal?

A. We still are doing it.

Q. I'm focusing right now on the period 1994 to 2000.

A. Yes.

Q. And is it fair to understand that for each of those studies that you would

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have ultimate responsibility for those studies?

MR. ANDERSON: Objection to form.

Go ahead.

THE WITNESS: In general, yes.

QUESTIONS BY MR. THOMAS:

Q. And I'm not --

MR. ANDERSON: Are you finished with your answer?

THE WITNESS: Just to explain this.

QUESTIONS BY MR. THOMAS:

Q. Sure.

A. Because there are several variations later on.

So there are some -- I usually have been involved in it, but the degree of my activity for defining every detail to this, this may vary a little bit.

Q. Did your animal test during this period from 1994 to 2000 have a standard methodology that you followed for animal implantation studies?

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A. There are general rules for animal to take care so -- worldwide-accepted rules for doing animal experiments so these have to be considered, of course. But if you ask specifically, we have developed different animal models, if you like to talk of models in relationship to animals. But there are --

Q. Not today.

A. There are some certain models. Because it is different whether you made a full abdominal wall replacement in a rat or whether you made a placement of the mesh only in the subcutaneous space, whether you want to investigate the reaction within the abdominal indicative, sometimes you need some bigger animals for the shrinkage, you need bigger animals in mice, you're very limited to do so, so there is a -- maybe half a dozen or a dozen different animal settings with -- where we try to make it in a standardized way.

Q. Did you standardize the sample preparations of the mesh prior to implant?

A. We permanently tried to

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optimize it. So we had -- in the beginning, we had other time points. Later on, we changed the time points a little bit. At the beginning, we made some explantation of the 42 days, then we later on learned that it's not necessary to do so.

But then we started a project, you have a protocol, and in this protocol, you have before -- you have to define how to handle the tissue that is explanted, when do it and so on.

Q. I think you misunderstood my question.

I'm talking about the front end before you put the mesh in the animal, was there a standardized procedure about how you prepared the mesh prior to implant?

A. There is a standardized procedure, yes.

Q. Does that standardized procedure include sterilizing the mesh?

A. I read that this was an issue in your discussions.

Q. I am sorry, where did you read

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that?

A. In the deposition, in the question with Klosterhalfen, you already discussed this issue.

Q. I think you mentioned it in your deposition last year, too.

A. That the sterilization?

Q. You sterilized the mesh before you did the implants.

A. We did it for the meshes that are -- where we got -- for PVDF meshes, for example, that we got from the FEG. At that time, they didn't have the facility to have sterilized. All mesh materials from Ethicon we got completely cut in a fashion 2.5 to 3.5 centimeters, and they're clear for use. They are sterilized, they are picked, they are cut, so that was part of our working meetings there to say that we need meshes five to five centimeters, and we got them completely for this purpose and there was printed on for experimental use.

So all these meshes that are coming from Ethicon, they are completely

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picked and sterilized for use.
Q. So just to answer the question, for the Ethicon meshes that you used in your animal studies for the period 1994 to 2000 --
A. Yeah.
Q. -- did you sterilize those yourselves?
A. No.
Q. Prior to use?
A. No. It was not necessary.
Q. For the period 1993 to 2000, did any of your work for Ethicon focus on pelvic floor?
A. No.
Q. And I distinguish between pelvic floor and stress urinary incontinence, so I ask the question again.
Did any of your work from the period 1994 to the year 2000 deal with the treatment of stress urinary incontinence?
A. No.
Q. Doctor, was there a time in your consulting relationship with Ethicon where you were consulted with respect to the

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use of mesh for stress urinary incontinence?
A. I only recall one, two conversations with Dr. Hellhammer when she informed me that there is an upcoming issue to use textiles in the pelvic floor and that I pointed out that when doing so, it would be very advised to use the principles of the VYPRO project for this purpose.
Q. Did she --
A. And later on this was -- we invited Professor Unsten at one of the Suvretta meetings to cover this -- the use of textiles in the pelvic floor as well, but we didn't do any research or any development with focus on these two.
Q. In the conversation you had with Dr. Hellhammer, do you know whether the mesh to which she was referring was in the pelvic floor or for stress urinary incontinence?
A. I don't recall that there was this differentiation.
Q. Did you understand in your conversation with Dr. Hellhammer that the

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mesh to be used in the pelvic floor was a new mesh?
A. I don't recall that I got any more precise information about what was ongoing there. I later on saw that in the area of 2001, Dr. Hellhammer prepared a big report where she outlined that VYPRO would be maybe a good solution for the use in the pelvic floor as well.
I assumed that this was a consequence of our conversation.
Q. Now, do you use pelvic floor to include stress urinary incontinence?
A. Please, can you rephrase it?
Q. Sure.
Pelvic floor can mean different things in different people and when I refer to pelvic floor, I refer to the treatment of cystoceles, rectoceles, pelvic organ prolapse.
I refer to other meshes for the treatment of stress urinary incontinence as a different category.
Do you separate the two?

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A. I wouldn't separate it in the way that you're doing. I know that there are -- from the clinical standpoint, there are different diseases. They're treated differently, they're paid differently. In the treatment of these things, if you're looking at Petros theory, you can treat everything with slings and with meshes, flat meshes. They acted differently. They have different task, they have different consequences. So incontinence can be a consequence of a prolapse as well. So there is a huge mixup of therapies and diagnosis and of treatments there.
I would prefer for the development of a device, for the treatment in the pelvic floor area that you have to -- I would prefer to differentiate between the flat meshes, tension-free, extended area or the slings that are intended to replace ligaments. So from the functional side, I think it is more helpful to differentiate between these two than to say pelvic floor is prolapse and incontinence is sling. That is

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not reflected by the various options that you have in the treatment and that -- but I know it's an ongoing discussion.

If you go to the Congresses for them, there are some preferring meshes. There are some meshes with slings or arms and some others are preferring slings as well so --

Q. At what point did you first study the use of slings for the treatment of stress urinary incontinence?

A. The first time I was invited by Professor Schulser, he made a local meeting there for his colleagues. He's a gynecologist and they -- they were starting the discussion in -- I don't remember the name. The year maybe 2004, so something around -- it was not come an issue whether to use other plastic materials in the pelvic floor, yes or not. And he invited me as a surgeon with the experience of hernia meshes which are the -- in fact, similar or the same as in gynecology to reflect our experiences, our knowledge there. That was the first

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time.

Later on, I had the opportunity -- he sent us some of his explanted slings. We made a publication together, then we made a review for the journal together. So that was the starting point to think of it and, yeah, today, if I regularly look to the literature and if you look to mesh, then meanwhile one-third of the publications are referring to pelvic floor mesh.

Q. The first work that you did in connection with slings for the treatment of stress urinary incontinence, you came at the invitation of your friend in Lucern; is that right?

MR. ANDERSON: Lucern.

THE WITNESS: Lucern.

QUESTIONS BY MR. THOMAS:

Q. Sorry.

And what was the purpose of your presentation there?

A. To present the experiences with textiles in surgery. The experimental

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results, how -- the characteristics. It's a terminology that is not familiar to surgeons, gynecologists and urologists. We have worked for ten years to introduce it in the surgical community, but the gynecologists and urologists still have a limited knowledge about these terminology and, therefore, I was invited by him, later on by Dr. Tunn in Berlin and later on by Ethicon in 2007 for the same purpose to present our experiences there.

Q. And is it fair to understand that you presented your experiences insofar as they relate to meshes and hernia repair to those people who are knowledgeable and experienced in the treatment of stress urinary incontinence to see the extent to which those two went together?

A. The main topic we present is what happens if you use a textile, what happens in the tissue and what are the main things that you have to consider when using a textile in the tissue and this is based on our experiences in surgery for hernia

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patients, on the preclinical studies, which are quite similarly used for many, many different devices. That has been the focus there.

Q. Have you ever studied the placement of transvaginal tape for the treatment of stress urinary incontinence?

A. No. No. We didn't study it ourselves and surprisingly when looking to the literature, I did not know -- I didn't find preclinical studies using comparison -- or studying the tissue reaction to slings.

Q. Is it fair to understand that, as you sit here today, you still have not studied the transvaginal placement of mesh for the treatment of stress urinary incontinence specifically?

MR. ANDERSON: Objection.

THE WITNESS: It is correct that we didn't study this specific application because there is no good animal model, but what we did extensively was we studied Prolene®. So that was without any doubts.

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QUESTIONS BY MR. THOMAS:
Q. At what point did you begin consulting with Ethicon on pelvic organ prolapse?
A. I never was asked by Ethicon to think about this issue.
Q. Okay. Doctor, have you ever been involved in any degradation studies for mesh, polypropylene mesh?
A. Involved in this direction that we -- that I advised to make the electron microscopy investigation that is later on published last year, I think, by Klink where he presented the electron microscopy, the comparison of PVDF and polypropylene. Because he wanted a manuscript dealing with the long-term result of a PVDF implant and, therefore, I thought it would be very helpful if they added this -- they tried to make an electron microscopy and add it to the manuscript and, in fact, they did it.
This was to my knowledge the only thing where I initiated a specific study in this work for degradation.

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Q. When you talk about this study by Dr. Klink, who is Dr. Klink?
A. He's one of our surgical coworkers.
Q. At the university?
A. At the university, yeah.
Q. Did you appear on the study with him?
A. Yes.
Q. Who else is on that study?
A. Some other surgical coworkers. I didn't recall everyone.
Q. And did you have any involvement with the design of the study that Dr. Klink conducted?
A. The placement of this material, the rough general plan, yes, but not specifically the details of this study.
Q. Tell me what involvement you had in the rough general plan of the study.
A. The principle idea, what to do or what to investigate, that is discussed with me so that I can say this is already done, this is insufficient to get published

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from my experience or what are the readouts, to define the readouts so we get a reliable result of such a study or whether it's insufficient to calculate the number of animals. Usually the discussion of this I'm involved in this.
Q. Was Dr. Klink a student at the university at the time?
A. No, he's a doctor.
Q. So he's a colleague of yours?
A. A colleague.
Q. Okay. Were you present with Professor Klosterhalfen when Professor Klosterhalfen had a debate with Clavé about his presentation on degradation of polypropylene?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I have been in Dijon at this meeting and saw the presentation of Clavé there, and I know that there has some dispute, academic dispute, between them. From my impression, it was not very

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intense, but maybe I'm a surgeon and in surgery it is -- we have another sensation for this. So, yeah, it was a conflicting while surprising result there that he shows not -- yeah, that what he shows there.
QUESTIONS BY MR. THOMAS:
Q. And what was it surprising in what Clavé reported?
A. Both in the extent of the degradation of the polypropylene, we didn't expect it at that time point and that he failed to see a degradation in the polyester. Because we already some years ago had seen it even by light microscopy and there wasn't this degradation. There was good literature from vascular grafts made of polyester that polyester is going to be degraded, and if someone is standing up and saying, "No, polyester is not degrading," that was something we could not understand at that time point.
It was not the fact that he showed the polypropylene was going to show

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this surface cracking because we are not absolute fan of either polymer, of these both polymer.

Q. After the meeting in Dijon, did you and Dr. Klosterhalfen talk about doing a degradation study on polypropylene?

A. There was a discussion. It was in the car of Klosterhalfen when we came back to this so we had some hours time to discuss this. And, yes, there appeared the idea that it would be necessary -- that it would be helpful, in particularly as we favor PVDF. So we are interested, and I think it would be an interesting question as well what happens in comparison to those. So a new field which you can study, that was the result of this.

Q. And did you work on designing a study to determine the extent to which polypropylene degrades as compares to PVDF?

A. No. I did not make a complete study. It was the idea that was raised there. It was the idea to take some implants, to go over there, to pay for it and to give some -- to get some images and to see

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what happens because at that time point, we didn't know whether it's sensitive enough or not. To make a study, to really study degradation process, what is impact, is it controlled, at what time point, what is the consequence, it needs a lot of more power and resources to make a real study of it.

Q. And when you say that, what needs to be done in the area of degradation to understand the nature and extent of degradation of polypropylene?

A. The problem of degradation is that it -- my experience of degradation is we had to do it -- we had some studies for -- with absorbable material and absorbable material in a reasonable time period shows some degradation. But then we have to define what happens there. There is -- there are chemical questions, the problem is the degradation after two years, how do we find this, animal models are limited. You can't use rats on it. There are only certain animals. You cannot -- you should have looked at various localizations at various

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tissues for different time points. You have to look in the presence of infection, in germs and in the absence of this material. You have to look with various very sensitive methods to look what is degraded, what happens there.

So a lot of these things, if you look to the literature dealing with degradation, there are a lot of methods, techniques that, of course, can be done, but it takes a lot of time, resources, money, to do so. It is simple to take some rats and look what happens after two years.

Q. And why is that a problem? Why didn't you take rats and implant the sutures and look after two years?

Why is that?

A. The rat is surviving only two years or three years. It does have different immunological capabilities than humans. It does not have the disease. You cannot implant it in the -- in a functional similarity to what is in humans. So any animal experiments just give you some small

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aspects. Some small aspects you can investigate in animals, some others not, so you have to make a network research degradation of the polymer.

So different -- many, many different aspects. Not one.

Q. Doctor, are you aware of a study in the literature today that you would identify as being reliable to analyze the extent to which polypropylene degrades in vivo in a human?

A. I cannot answer to what extent in vivo because it should be more precise to what conditions.

The only thing that I can really good or -- I can answer is the question does it degrade, yes or not, and meanwhile, I think if you look to all of the arguments, to all of the studies, there is to -- I'm certain, I'm convinced that there is degradation to the polypropylene when you implanted it into -- in tissues, yes.

Q. Is that based upon the scanning electron microscopy?

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A. It is based on all these various publications that meanwhile have shown these -- these surface cracking or these degradation, these morphological changes, included the investigation that are done for this. All of this is in agreement. It's consistent. All together it makes clear there is some and it should have been investigated so that you have an understanding by the manufacturer, not by the surgeon, not by the patient.

Q. When you and Dr. Klosterhalfen came back from Dijon and talked about conducting a degradation analysis, did the two of you decide what to do?

A. I recall that we discuss how this can be done and this can be done at human explants to bring them somewhere, yeah. That was the discussion there.

Q. And there came a point in time when FEG paid for certain testing, correct?

A. They initiated this thing.

Q. Did you suggest it to them?

A. To do this?

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Q. Yes.

A. It was a discussion among Obolensky, Klosterhalfen and me that these are interesting findings. The FEG has been participating in Dijon as well so they realized that there is maybe a new topic there and they wanted to have own experiences in this field and, therefore, they initiated the study.

Q. Did you consult with FEG about how to conduct the study?

A. I'm not an expert in electron microscopy, that is in the field from Professor Klosterhalfen. I can just say, yeah, should be done in explanted mesh materials, yes, but I'm not able to give advice on how to do an electron microscopy.

Q. Did you provide any explants from your collection to FEG to test?

A. Not that I recall.

Q. Have you ever provided to FEG any mesh explants for them to analyze that came from your collection at the university?

A. Not that I recall.

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You mean the human?

Q. Yes.

A. Human.

Q. The answer is the same?

A. For the humans, not -- they didn't get any specimen for further investigation. Of course, in the experiments and project I do together with them, we share the results of these.

Q. The animal studies?

A. The animal studies, yeah.

Q. But you've never shared with them a human --

A. Human explants, no.

Q. Dr. Klosterhalfen testified this weekend that he did give some of the explants that he had from his collection for FEG to study.

Did you have any involvement in consulting with how those explants would be prepared for analysis?

A. As I told you, it was not my expertise to say how a section has to be prepared for performing a electron

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microscopy.

Q. Have you ever cleaned a mesh explant?

MR. ANDERSON: Objection to form.

Go ahead.

THE WITNESS: We did it. We did it from cells and from proteins to get the permanent structure, to demonstrate the permanent structure of these materials, we sometimes did it.

QUESTIONS BY MR. THOMAS:

Q. And did you do it -- strike that.

When did you do that?

When did you clean tissue to learn about the permanent structure of the material?

A. Sometimes in between the first ten years of our research.

Q. Okay. How did you clean materials?

With what kind of substance did you clean it with?

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A. We usually use some proteases to do so.
Q. Tell me what a protease is.
A. A protease is a protein that's able to degrade other proteins so they can remove or get soluble in a liquid solution.
Q. Are there different kinds of proteases?
A. Yes.
Q. I figured.
A. Numerous. I don't know them all by heart.
Q. What type of protease would be appropriate for cleaning human tissue off an explant?
A. I don't recall. I would have to look to the protocols.
Q. And where would you look to figure that out? Would it be in the published literature?
A. Yeah, there is -- the first man who did it was maybe Coda. It was an Italian publication, in Hernia, together with Ben David, a Canadian surgeon, and they published

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for the first time the change of pores after explantation and they removed all tissues from their explants.
Q. And what was the finding of that study?
A. That when you're doing this and you're removing all of this tissue -- all of these tissues and make them a photograph of these meshes, the pores are bigger than in the textile -- in the pristine form, I think is the word.
MR. ANDERSON: Pristine, yeah.
QUESTIONS BY MR. THOMAS:
Q. So what kind of mesh was tested, do you know?
A. It was usually large pore, heavy-weight meshes, I don't have any detail. Several. They have maybe 20 different explants and then they are analyzed.
Q. Did Coda and Ben David give an explanation as to why the pores were larger after cleaning than they were pristine?
A. Of course, they tried to give an explanation. There always is a huge

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discussion there.
Q. Sure.
A. But I don't recall it.
Q. Okay. And this is Coda, C-o-d-a?
A. Yes, C-o-d-a, Italian, and it is in Hernia published and coauthor I know is Ben David. Robert Ben David.
Q. How long ago was this, do you know?
A. '99, 2000.
Q. Did you look to the methods used by Coda in his publication to learn how to remove the tissue from the explants where you've done that?
A. I remember that we have -- that we look in the literature to find some references to see what to -- what to do with these tissues and how to remove the tissues, but I don't recall -- I recall that we only found three, four publications at that time when we did it offering some protocols to do these experiments, but I don't recall why we did and for what purpose. I cannot imagine.

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Q. Do you know whether the methods used by Coda and Ben David in their study are accepted today as an appropriate method to remove tissue without damaging the mesh material?
A. I never -- and I extensively looked through the literature. I never found a statement which is close to what you are questioning.
Q. Okay. Dr. Klosterhalfen testified this weekend that the explants that he supplied to FEG were cleaned before analysis.
Did you have anything to do with deciding a method by which the explants would be cleaned?
A. By what? By --
Q. Did you have any contribution -- strike that.
Did you tell Dr. Klosterhalfen or anybody your ideas about how to clean the explants before they were analyzed by scanning electron microscopy?
A. I don't recall any specific

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device there and, of course, it is in his field how to prepare sections for electron microscopy. I just recalled some discussions whether, yeah, there are some pros and some cons to clean it and not to clean it and so, yeah.

Q. What are the pros and cons?

A. To clean it or not to clean it, if you clean it, you -- you expect that you only have the polymer there without any alteration by some attachments from outside.

If you clean it, you may get -- as a consequence, you may get some damage by cleaning process. So whatever you're doing.

Q. Did you see the results of the FEG testing of the Klosterhalfen explants?

A. Some of these. Not -- I'm sure I didn't see all of them, but I saw some of these images.

Q. Do you have copies of those images?

A. They're included in my presentations there. And it is --

Q. And the presentations you're

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talking about, the presentations that you make to --

A. And you have and is similar images as Klosterhalfen presented.

Q. Okay. Do you have any study analysis of the people who conducted the scanning electron microscopy that would reflect how they prepared the samples and took the photographs, the images, that you now have in your presentations?

A. I didn't saw the protocols, how they did the analysis.

Q. Do you have any paperwork at all from that study?

A. If you call it this pilot study from the FEG, I didn't have any.

Q. Okay. Do you have any documents other than the images that you've described that deal with the FEG analysis of the Klosterhalfen explants?

A. No, I don't have.

Q. Dr. Klosterhalfen also told us that FEG contracted with a lab in Bulgaria to conduct some animals studies with mesh.

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Are you familiar with that study?

A. I know that there is a -- there has been a project together with -- with an urologist from Neuss, close to Dusseldorf where you're going tomorrow, Dr. Otto, and if you look to the -- and this has already published, Otto and Dr. Klosterhalfen together they have published some article dealing -- because he's working on the -- to find better mesh materials for the pelvic floor area. I know that they performed this study in collaboration with this Hungarian lab and these are mentioned as coauthors. So I don't recall the address, but if you're going to this article, they're mentioned as coauthors.

Q. Okay. So you understand that the study conducted by FEG comparing degradation of PVDF and polypropylene has now been published by Dr. Klosterhalfen and Dr. Otto?

MR. ANDERSON: Objection to form.

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QUESTIONS BY MR. THOMAS:

Q. Is that right? Is that what you said?

A. No, that is not right.

Q. I am sorry, I misunderstood you.

A. You asked me whether there was a collaboration. He mentioned a collaboration with a lab in Hungaria. That was the question I tried to answer to this and, therefore, I said, yes, there was this collaboration with this lab in Hungary. It does not -- or it is -- it's not in relation to the electron microscopy study. It's completely different.

Q. And maybe I better start over.

Dr. Klosterhalfen testified this weekend, I believe, that at the same time or about the same time as FEG asked the lab here in Aachen -- GFE I think it is?

A. Yeah.

Q. -- to conduct electron microscopy of some of his explants, the FEG also conducted an animal study. I believe he

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said Bulgaria, maybe it was Hungary?
A. Hungary. I don't know Bulgaria. It may be.
Q. Where there was a rat study conducted with implants of an FEG mesh, their IPOM mesh that had both PVDF and polypropylene strands side-by-side and the rat study was conducted there and results reported back and he uses some of the images from that study in his presentation.
A. Ah, now I get it. It was -- I think it was the animals. It -- it was the animals in the report of Klink.
Q. So do you think the Klink study we've already talked about --
A. They've been done in Russia, in Moscow. To be precisely, I have to look to all of these various things.
Q. Okay. Are you aware of a study that FEG conducted in Bulgaria where they implanted mesh from their IPOM mesh into rats to compare the degradation of polypropylene versus PVDF?
A. I am not aware of a study made

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in Bulgaria. I know that there has been some studies in collaboration with Professor Ettinger in Moscow where they implanted some IPOM meshes there. I'm not -- I do not recall that this was a study to study degradation of it because this would mean a lot of other things to study degradation. But this -- these explants have been used to demonstrate whether there is a surface cracking, yes or not.
Q. I'm not talking --
A. So this is an additional point and this was as a result of this, we got this image where you have the PVDF filaments and the polypropylene filaments after four months implantation in an animal.
Q. Where did you get those?
A. Where?
Q. From what study?
A. This is the image -- that is an image we got -- yeah, I think that is from the study from Klink where we both have these.
Q. Yeah.

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As I recall Professor Klosterhalfen's testimony, he said that came from the Bulgarian study.
Is that the same as Dr. Klink's study?
A. Maybe we both have incorrect or incomplete information about this.
Q. Do you --
A. So we have -- we have to -- yeah, we can try to clarify this, so obviously, I have not sufficient information to be -- to say exactly there.
Q. Okay. So if you get a question at your next presentation where did this come from, you're not sure?
A. Then I will be sure.
Q. Do you know whether FEG adds any chemicals to its polypropylene to stabilize the polypropylene?
MR. ANDERSON: FEG to its polypropylene?
QUESTIONS BY MR. THOMAS:
Q. Yes.
A. Yes, they have polypropylene as

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well.
Q. Yes.
A. So I don't know whether they use additives for polypropylene, but all I know is that you have to do it because it is not possible to use polypropylene as a pure polymer for the suture manifictation. So in its polypropylene, they, of course, should have some additives. I know that in the PVDF filaments, that is pure. There is no additive.
MR. THOMAS: Take a break for a second?
MR. ANDERSON: Yeah.
(Off the record at 3:10 p.m.)
(Klinge Exhibit 9 marked for identification.)
QUESTIONS BY MR. THOMAS:
Q. Doctor, I'm going to hand you what I've marked as Deposition Exhibit Number 9.
Deposition Exhibit Number 9 is a document titled "Ethicon Surgeon Panel Meeting Mesh, Suvretta House, St. Moritz,

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January 18, 2003."

Have you seen this document before?

A. I've seen it just recently, yeah.

Q. In preparation for your deposition?

A. Yes.

Q. Did you attend a meeting at the Suvretta House Hotel in St. Moritz on January 18, 2003?

A. Yes.

Q. How did that meeting come about?

A. It was at the occasion of the third Suvretta meeting that has been organized in St. Moritz. There was a -- yeah, meanwhile, there has been a tradition to make this meeting there and this meeting ends one o'clock p.m. on Saturday and afterwards, Ethicon organized this additional meeting there.

MR. ANDERSON: Counsel, can I just ask why the document has been

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redacted?

MR. THOMAS: I have no answer.

MR. ANDERSON: Okay.

MR. THOMAS: I don't know.

MR. ANDERSON: So we'll send you a note asking whoever on your team to give us an explanation as to why it's been redacted. Okay?

MR. THOMAS: Yeah.

MR. ANDERSON: Thank you.

MR. THOMAS: And I apologize for having no idea.

MR. ANDERSON: I understand.

QUESTIONS BY MR. THOMAS:

Q. Doctor, what is -- who sponsors the annual Suvretta meeting?

A. I have to correct. I'm not sure whether I saw this document. The first page, yes, I've seen the first page. If I'm looking to all these text pages here afterwards, these commence to this, I didn't work through this consciously until now.

Q. Okay.

A. That I'm sure.

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Q. Who sponsors the Suvretta meeting in St. Moritz?

A. The Suvretta meeting first -- the first Suvretta meeting was in January or February 1994 and at that time, it was sponsored by Ethicon, Covidien, Brown, maybe three, four major manufacturers with the idea to collect all important persons that can discuss about hernia. Because at that time, there was the upcoming new techniques with meshes, the endoscopic, the Lichtenstein and they wanted to have their people discussing this from the entire world and because this is very -- they choose a very nice place, but this was very expensive and, therefore, four companies are putting the money together. This was the first conference.

The second conference, the only sponsor was Ethicon, and subsequently all other meetings were sponsored only by Ethicon Hamburg Norderstedt. I don't know. I think it is a marketing device, but -- department, but they have different people in charge to provide the money for this conference.

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Q. And has the focus of the Suvretta conference been on hernia repair?

A. The focus of all of these Suvretta conferences is with focus on hernia repair. First was inguinal hernia. Then we have incisional hernia, recurrent hernia, meshes, and last, I don't recall in the moment, but all has been published as books. All books have been -- have been bought by Ethicon Hamburg Norderstedt. They always got 1,000 or 2,000 of these books and you can buy it. It's free. All of the presentations are written in this book was a lot of work for this, yeah.

Q. So as I understand it, you don't recall -- you recall seeing the cover page of Exhibit Number 9, but you don't recall the rest of the document.

Is that fair?

MR. ANDERSON: Said he just didn't read it in detail.

THE WITNESS: So if you ask me some specific thing here, I need some time to think about it, yeah.

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QUESTIONS BY MR. THOMAS:
Q. That's fine and we'll do that in just a second.
Going back to the first page, who is Dr. Zollinger, Robert Zollinger, the moderator?
A. I do not recall. Yeah, Robert Zollinger is, of course -- no, I don't recall.
Q. Now, on the surgeon attendees, there's Professor Schumpelick, Dr. Klosterhalfen, Dr. Conze, Dr. Klinge, Dr. Stumpf and Dr. Junge.
Would you consider those to be part of the Aachen group?
MR. ANDERSON: Objection to form.
THE WITNESS: I wouldn't object.
QUESTIONS BY MR. THOMAS:
Q. And where does Dr. Conze fit in the group, what expertise does he bring to the group?
A. I guess that this was

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invitation of the entire Aachen group. Of all of the Aachen participants that have been at the Suvretta meeting at that time because all of the other participants left already. So we have to stay there for another day to Sunday and, therefore, I guess that the invitation and the surgeon attendees included all of the Aachen members that were -- had the duty to organize this conference and, therefore, we have been there.
If -- so to my recall, there was not a specific task for Dr. Conze or a presentation or something like that. If you ask me what is the focus of the work that Conze had done with this, he focused on the laparoscopic placement of these meshes. So he published some IPOM studies in a rabbit model. This is his --
Q. And he is a hernia surgeon?
A. He has been -- yeah, he is a surgeon and he has been working at the university until summer last year and now he left the department.
Q. Who is Dr. Stumpf?

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A. Dr. Stumpf is a surgeon. His focus is more wound healing, wound healing for after bowel resection and we made several publications together with him. Some very experienced surgeon who left two, three years ago who left the university and now is head of the department in southern Germany.
Q. And Dr. Junge?
A. Dr. Junge at that time was a young resident, meanwhile he's professor as well. Very enthusiastic and interested in making research, very active. So I published about 50, 60 reports together with him because it was a pleasure to work with him.
Q. And what is his area of practice now?
A. Visceral general surgery. The main focus of our department is cancer in the upper GI and liver transportation. So that is his surgical focus at the moment.
Q. Now, down below the list of surgeon attendees, there are a list of Ethicon observers.
You've told me that you've had

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interaction with Brigitte Hellhammer, Boris Batke, Dieter Engel.
Have you had contact over the years with any of these other people of the Ethicon observers?
A. Though I have a limited memory, but I remember Ohad Lavi and Paul Campbell. There has been some periods where we have a closer contact. Ohad Lavi was someone, I think he was responsible for the educational program of Ethicon and, therefore, he was a part of the -- of the meetings we have at our department where Ethicon brought about 20 surgeons to our department so that we can demonstrate how to operate incisional hernia and Lavi was one of the team, I think, that was responsible for this program. What we call team hospitance.
Q. Do you remember this presentation that you made at this meeting ten years ago?
A. Not the -- not the slides in detail.
Q. Turn the page, please.

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The page -- top of the page says, "Notes of Panel Discussion, Presentation One, Dr. Klinge, Light Mesh Theory and Science."

Do you recall giving the first presentation of the Ethicon conference in 2003 at the Suvretta conference?

A. Yes.

Q. And it appears that you're talking generally about mesh and then you have a lengthy discussion about VYPRO.

Is that fair?

A. Obviously, it seems so, uh-huh.

Q. Well, do you recall if the focus of your presentation was on the benefit of VYPRO mesh?

A. The benefits of our presentation is the light-weight mesh theory. That means that the larger the pores, the lower the risk. So that is -- and VYPRO is our example where we for the first time could realize this principle.

Q. At the time that you're giving this presentation in January of 2003, are

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there other meshes on the market that you would characterize as light-weight, large pore?

A. At that time -- if I remember correctly, that was the meeting where ULTRAPRO™ was demonstrated or shown for the first time.

Q. If you go to page 5.

A. Dr. Klosterhalfen, yeah.

Q. It talks about Edelweiss and the Monocryl. They're talking about ULTRAPRO™, I think.

But at the time, were there any other light-weight, large pore meshes on the market, January 2003, about which you were aware?

MR. ANDERSON: Objection. Other than what he just stated?

THE WITNESS: So far I recall, the first successor of VYPRO was ULTRAPRO™ and then all other competitors are coming later with their light-weight variance. The tie mesh is later. So at that moment,

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VYPRO was the prototype of this conception.

QUESTIONS BY MR. THOMAS:

Q. That's what I'm trying to get to. Is January 2003, the one that's in the market at that time is VYPRO?

A. Yeah. But our concern, whatever we made the presentation not for VYPRO as a product, but VYPRO as an idea of a conception. That is what is expressed in the title, light-weight mesh theory.

Q. VYPRO ultimately was not successful.

Would you agree with that?

A. It was totally -- the VYPRO concept was successful as nothing -- as almost nothing else.

Q. But as a commercial success --

MR. ANDERSON: Let him finish.

MR. THOMAS: I didn't mean to interrupt him.

THE WITNESS: As a commercial thing, it was not -- for several reasons, it was not successful.

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QUESTIONS BY MR. THOMAS:

Q. What are the reasons that you understand that VYPRO was not a commercial success?

A. First of all, the VYPRO, we have been limited -- when doing the VYPRO, we have been limited by the fibers that are available for Hamburg Norderstedt. And that was a reason that we had to use five polypropylene fibers because Dr. Hyntsch was not able to provide any others. Therefore, there was some not multifilament, but polyfilament, increase the surface by the VYPRO. That makes it a little bit more floppy. So we have been limited in the construction of the VYPRO and this always has a disadvantage that some surgeons considered this as a multifilament because of the enhanced risk for infection. This is a structural disadvantage.

Then it has been the first on the market in this one. So it means that all surgeons has to change their attitude to think, not to think any longer during the OR,

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it's strong, it must work very well, but to think that a floppier one should be better. And this takes a lot of conferences, a lot of publications, a lot of time. So it is a matter of time as well.

But the most important thing that VYPRO was not a success was that it was replaced by ULTRAPRO™. So ULTRAPRO™ was looking nice. It's blue and it's white, it's pure monofilament, it doesn't have the Vicryl, it has a Monocryl, which is less inflammatory and fibrotic reaction and, therefore, the ULTRAPRO™ is -- has been a hit for them. And if you look to the -- I don't know whether you have the says rates in this, but I don't have it either, but I'm sure ULTRAPRO™ meanwhile is the current mesh and it's light-weight, large pores, 3, 4 millimeters, so the conception is very, very successful, but in the form of the ULTRAPRO™ for hernia surgery.

QUESTIONS BY MR. THOMAS:

Q. Did anyone in the Aachen group have any role in the development of

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ULTRAPRO™?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: I don't know anyone. Maybe Professor Schumpelick himself, but none of my colleagues or -- I don't know any.

QUESTIONS BY MR. THOMAS:

Q. On page 2 of Exhibit Number 9, under "Mesh Complications," under "Fibrosis," it says that, "There will be fibrosis either through scar net or bridging."

What is scar net?

A. At that time point, we tried to figure out a good terminology to describe the different appearance what we -- we are seeing there. Just to say there is fibrosis, yes, not -- that is not sufficient enough, and at that time point, it was an attempt to get a better -- to make it easier to understand the differences and there was on the one hand the scar plate. The scar plate where you have scar all around the mesh and this was -- this was in comparison to the scar net. And the

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scar net means that the fibrosis is limited to the peri-filamentary area where you have pores filled with sket -- with fat tissue. So when you made an imaging of these, then you will have a net of scar tissue just around the fibers and in between is the physiological tissue. This is scar net. And the scar plate would mean everything is integrated into scar.

It is a difficult terminology and later on we didn't -- we replaced this one, I think. I cannot remember that we today are talking about this -- it is too difficult for the audience to understand this.

Q. Okay. And bridging, what is bridging in this context today? In January 2003?

A. The bridging is the filling of the pores by scar tissue.

Q. At what point does scar net become scar bridging?

A. Our results at that time point until 2003 indicate that there is a -- yeah,

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that in the area of 3 millimeters, you don't have any bridging, if you have 3 millimeters there. If you have 200 microns, 600 microns, you always have this sort of bridging there.

Q. Okay. Continuing on, it says, "Granuloma forms around the individual filaments, and if pore size small enough, there will also be bridging, paren, or fibrosis, between the pores which forms a scar plate. When the pores are farther apart, there is no bridging effect with the pores being filled with fat tissue. The limit for the pore size would appear to be 6 to 800 microns. Below this, scar plate; above this, scar net."

What does that mean?

A. If you have small pores, without sticking to the microns, if you have small pores, you have this foreign body reaction around the filaments. They're releasing cytokines, they're attracting fibroblasts and you see if you made a microscope that you only have collagen and inflammatory cells in the pores.

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When you have larger distance between the filaments there, then you see that the pores in the middle, they contain fat tissue which usually is the physiological local tissue there in this area, but it is not any longer filled completely by scar tissue. This is the main difference there.

Q. So the scar net is the desired response of the mesh to the tissue; is that fair?

A. It is an attempt to describe the nonbridging, the good mesh, yeah.

Q. It's the result that you hope to achieve when you implant mesh, you want a scar net, correct?

A. We don't want to have a scar plate. We want to have this what we call at that time scar net, yes.

Q. Okay. And did you tell these surgeons back in January 2003 that below 800 microns in pore size you would get scar plate, 6 to 800 microns, correct?

A. As it is written here, appeared to be so with some limitations. The risk is

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high for scar plate below this range, yeah, that is correct.

Q. And did you tell --

A. It depends from the pore size. The risk for getting a scar plate depends on the pore size. That is the message of this slide.

Q. Well, did you tell these surgeons and these people from Ethicon in January 2003 that above 6 to 800 microns you would get a scar net?

A. You have the chance with larger pores. With larger pores, the basic message is that with larger pores, the risk for scar plate is less and the risk for scar net -- to achieve a scar net is better. I know it would be completely wrong to say that there is one figure 600, 800, 900, 1,000. If you have 1,001, it is good, and if you have 999, it is bad. That is not what we tried to bring to the audience. The larger the pores, the lower the risk for a scar plate is there.

There seems to be a significant range where it seemed to change or -- yeah,

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where you see these differences and this is in the area of 600, 800, 1 millimeter. It evolves -- it changed a little bit because it depends a little bit from the animal experiments, from the tissue, from the material whether you want to have some safety limits there in this area.

Q. My question is pretty simple and pretty direct.

Do you recall telling these people at this meeting in January of 2003 that above 6 to 800 microns you would -- of a pore size you would expect to get a scar net?

A. I do not recall as I told you exactly that the moment where I told this. I know that I, in very many presentations, I focused on the fact that pore size is decisive and that there is a limit in the range of 600, 800. So sometimes it is -- yeah, we use 1 millimeter because we want to be sure that we have even less risk to get some problems, but the message is that pore size is important and that you have to use large pores. That's it.

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Q. As written here, as I read it to you, "The limit for the pore size would appear to be 6 to 800 microns. Below this, equals scar plate; above this, equals scar net."

Is that a true statement of your research as of January 2003?

A. I read the limit for the pore size would appear to be, so some uncertainty is in the sentence there.

Q. Yes.

A. And I recollect that we have made some examination, we have some measurements where we marked it in this area of 600 to 800 microns, yes.

Q. So that's a true statement of your research as of the time this was given?

A. At that time point, we had some data indicating that there is a limit.

Q. Well, is that the best summary of your research as of January 2003 that you're presenting to these surgeons in Exhibit 9?

A. As I told you, the best summary

would be if you stress on the point that large pores are helpful and small pores are dangerous.

Q. Is the information that's stated in Exhibit Number 9, "The limit for the pore size would appear to be 6 to 800 microns. Below this, equal scar plate; above this, equals scar net," is that wrong?

A. It is incomplete.

Q. Okay.

A. If you are -- what does it mean? Wrong or right. At that time point, it was our present knowledge there. Meanwhile, we know that pore size is much more difficult to define.

(Klinge Exhibit 10 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, I've handed you what's been marked as Deposition Exhibit Number 10. This is a copy of your curriculum vitae. It was produced to us in this case.

Is this a current CV?

A. Yes.

Q. And the first page sets out your employment history and the members of societies of which you're a member? Let me start over again.

The first page sets out some general information about your education, employment history, scientific work and the professional societies of which you're a member and the rest of it is your publications, grants and patents.

Is that fair?

A. You have a question?

Q. Yeah, I asked you if that is what it was. Your CV with your -- as I described it.

A. Yes.

Q. Let's talk about your patents on the last page, page 41.

The first patent is the one we talked about some today, the PVDF mesh on a patent with FEG; is that correct?

A. Yes.

Q. What are the other patents that you have here? Just describe them for me

generally, please.

A. That are mainly other modifications of -- that are using PVDF mesh, textile meshes, but they're modified.

Q. Okay. And these are all modified of the original FEG patent; is that right?

A. I don't know whether it's a correct term to say modified. It's in addition. Whether it's another patent, I really -- I'm -- whether it's another new or whether it's a modification and attachment, a supplement of an existing, I don't know.

Q. Okay. Are all of the patents that you have on page 41 through -- strike that.

Are all of the patents that you have on page 41 of Exhibit 10 with FEG?

A. Yes.

(Klinge Exhibit 11 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, I'm going to hand you now what I've marked as Deposition Exhibit

Number 11.

Deposition Exhibit Number 11 is the expert report that you've prepared for this case, correct?

A. Looks like.

Q. And as part of your work in this case, were you asked to look at the Prolene® mesh that is used for the treatment of stress urinary incontinence?

A. Yes.

Q. And I believe from earlier deposition, I understand that you have used Prolene® mesh approximately three or four times for the treatment of hernia repair?

A. Half a dozen, yeah. Five times I told last year.

Q. And for what purpose would you use Prolene® mesh for the treatment of hernia repair?

A. Today?

Q. At the time that you did it.

A. At that time, we used Prolene® mesh, Marlex meshes. At the beginning of the mesh -- of the use of meshes for hernia

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repair so they're -- yeah, when we have been in our learning curves, they have been using this for hernia repair. Today we never would do so, but only with a very limited indication for these materials.

Q. Prolene® mesh and Marlex mesh are two different meshes, aren't they?

A. Two different meshes. Marlex is from BARD and Prolene® is from Ethicon.

Q. And they have different --

MR. ANDERSON: Let him finish, please.

THE WITNESS: Prolene® is even more heavier than the Marlex, and Marlex has been the predominant mesh in the beginning of the '90s in Germany.

QUESTIONS BY MR. THOMAS:

Q. And the pore design is different, too, isn't it?

A. The pore design is different, yeah. But you -- you almost never find some -- or two different devices that matches completely.

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Q. So in the five or six times that you used Prolene®, you said you used it for certain indications.

What indications would you use Prolene® for when you were using it in the '90s?

A. Today?

Q. In the '90s.

A. In the '90s, see, before our work in the '93, '94, we used it as a standard device for reenforcement of large incisional hernia. The only alternative at that time or the other alternative at that time has been Marlex. So to use Marlex or Prolene®, that was the option for.

Q. How many times did you use Marlex in hernia repair?

A. Maybe 20, 25.

Q. Why did you use Marlex more than you used Prolene® in hernia repair?

A. Marlex at that time has been the predominantly used mesh material in surgery and in our hospital. I guess it has about 70 percent of incisional hernias when

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using meshes use Marlex.

Q. Were you trained to use Marlex in the repair of incisional hernias?

A. You can say so, yeah.

Q. Why? Why were you taught to use Marlex for the repair of incisional hernias?

A. The time period in the '90s, at the beginning of the '90s or in the late '80s, I was trained to do only suture repair, and in the beginning of the '90s, there was an upcoming feeling that suture repair is not sufficient and there was experience that meshes -- reenforcement of tissues but the meshes can be beneficial, and the meshes available at that time was mainly the Marlex mesh. So you have to decide in surgery to try to use -- if you want to try or to use a mesh because of recurrences, if you want to have an additional reenforcement of the tissue, you are using the Marlex mesh. That was our option to do so. And then we saw increasing number of seroma or some patients with serious complaints. And that -- and we

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had to make some revisions and saw the appearance of these meshes at that time and that was a reason to start our thinking that it can be improved.

Q. Why did you ever use Prolene® instead of Marlex?

A. I don't recall exactly because it was available. At that time, you ask for a mesh and you get the mesh from the nurses there. It was not popular, and it was not -- yeah, most of the surgeons at that time really didn't realize that they have to be very careful in the selection of the mesh material. It was the time period before we started to work on it and there they took the mesh that was available.

Q. Before 1993, did you have any information that caused you to choose between meshes for various indications in the hernia surgery you performed?

A. No. No, I don't recall that there was any -- any direct selection of the mesh materials, no.

Q. So are you telling me that you

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just used what was put in your hands during the surgery?
MR. ANDERSON: Objection. Form.
Go ahead.
THE WITNESS: We asked for a suture and we got a suture that was bought by the hospital that was provided and we asked for a mesh and we were provided by this mesh. There wasn't any other alternative. It was allowed to use these meshes. It was a description to use these meshes in the patients and, therefore, we used it.
QUESTIONS BY MR. THOMAS:
Q. Well, when you used sutures, you could order different size sutures, couldn't you?
MR. ANDERSON: Objection to form.
THE WITNESS: As a surgeon, you don't start to -- you have some specific sutures that are best suitable for your specific purpose and

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a good nurse in the interaction with you knows what you want to have. There are some certain standards in every hospital, may be different from hospital to hospital, but then you get the suture material.
Whether there is a difference with an absorbable material, whether you take it from Ethicon or Covidien or from Brown or from other manufacturer, you don't care.
QUESTIONS BY MR. THOMAS:
Q. Prior to 1993, did you care what kind of mesh that you put in a patient?
A. 1993?
Q. Before 1993, when you were doing hernia surgery, did you care what kind of mesh you put in a patient?
A. At that time, we didn't have a satisfying information about the risks and what happens there.
Q. Did you care before 1993 what kind of mesh you put in a patient when you're doing hernia surgery?

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MR. ANDERSON: Objection to form.
Go ahead.
THE WITNESS: No. The only thing is we care whether to make mesh, yes, or to take a mesh, yes, or not. That was a big issue and a big discussion at that time, but if you decide to use a mesh, the selection of the best mesh, that was not an issue.
QUESTIONS BY MR. THOMAS:
Q. Was Marlex the leader in the market for mesh at the time that you were trained in hernia surgery?
A. Yes. To my knowledge, yes.
Q. So if I understand correctly, those sometimes that you used Prolene® mesh for hernia surgery, it wasn't because you chose it, it was because you were given it?
A. Uh-huh.
Q. Is that true?
A. Yes.
Q. As a surgeon using Prolene® mesh, in handling it and in using it with a

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patient, did you notice any difference compared to Marlex mesh?
A. It's a long time ago. Only -- not really.
Q. Okay. Now, you know from your report that there have been three different versions of Prolene® mesh, correct?
A. Yes.
Q. And there is the first generation Prolene® mesh, the original Prolene® mesh.
Are you comfortable if I call it the first generation mesh?
A. Sorry, last sentence.
Q. What do you call the original Prolene® mesh, how do you describe it?
A. The old Prolene®. In fact, we have realized within the last two years independent from this litigation that there -- that we are offered or that we have images of Prolene® with a lot of variations, and there has been some -- obviously, there has been done some modifications of the Prolene®, but it was not ever communicated to

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me in a clear way until I've seen this Excel sheet where the time course were. That was the first time that we really realized that there has been different modifications of the Prolene® mesh.

So, therefore, this was not a common issue in our discussions to see all of these differences. We know that there has been a PHS with the specific textile structure. We know that there has been some changes from the old Prolene® to the new Prolene®, but it was not communicated very well which -- when this was done or whether we have the old one or the new one so.

Q. When did you first appreciate that there had been three versions of Prolene® mesh in the last 20 years?

A. I know it already about ten years ago. I know it that there has been a modification, but we didn't make any comparison or analysis or so. And so finally two years ago we started -- I recollected images from textile meshes and there I got increasingly confused about the terminology

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what is done. And if you are looking to the published literature and some of the authors presented some of these textile images at the beginning of their report, you see that there is an entire mixing up of the terminology of this.

So I was really happy when I saw these Excel grid so that you can see this one.

Q. Okay. Do you have an understanding as you sit here today during what periods of time each Prolene® mesh was used for hernia repair?

A. I've seen in this document that in the '90s -- most of the '90s the old Prolene® was available there. And that was in accordance to my pictures from my time with the Prolene® with this specific textile structure. So I assumed that at this time we only have been looking at the old Prolene®.

Q. At what time did the old Prolene® for hernia repair change?

A. According to your documents or the Excel sheet I've seen, it was about '98,

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'99. So then the second version and then the third version is --

Q. Before you saw the documents from this litigation, did you know when the -- what you call the old Prolene® changed to the next Prolene® in 1998 or 1999, did you know that?

A. Did you ask me why or when --

Q. When, when did you figure that out? Just in the last two years?

A. It was in the -- as I told you, I know in -- I got the information in 2000 in one of the discussions with the Ethicon guys there that they changed it, but we never made any comparison old Prolene® or new Prolene®. I was just informed about it. It was not an issue to think about it at that time. But in the past five years, we made some analysis, more analysis, and now we sought -- we looked to the images that there is a mixing up of these things and then we realized this.

Q. What do you mean by that, "The last five years there had been a mixing up of things"? I don't understand that.

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A. The terminology, if you -- there are a lot of publications here claiming that they are investigating Prolene® mesh. And if you look to the images in the literature there, you sometimes find the old Prolene®, sometimes you find the new Prolene®, but in the text is always Prolene®. And it was very difficult for me to find out what is it. What is it -- the major difference.

Other example is SURGIPRO. SURGIPRO is awful for me as a researcher because SURGIPRO you have five, six, seven variations, and it is not indicated by the name alone. So and the same with Prolene®, if you -- if Ethicon had chosen another name, it would be more simple, but for the audience, for the public, it is still Prolene® and that makes it so difficult.

Q. Which Prolene® mesh did you use in your hernia repairs the five or six times you did it, do you know which one you used?

A. 1993. So it has to be the old Prolene®. I'm sure all these animal

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experiments, what we did with the materials we got from Ethicon that were the old Prolene®. From the figures, from the images that I made at that time, it is consistent that it's an old Prolene®, but it was never an official time point where you can say from this on, the world knows it's another Prolene®. We never had this time point.

Q. Now, when you conduct an animal study and you use Prolene® mesh in your animal study, you describe the mesh that you're using and the specifications of that mesh, don't you?

A. We had been the first in our reports in 1995, 1996 where we introduced these -- the values of the textile characteristic of these meshes that has been done at the Institute for Textile Engineering where we put these meshes and it happens in 1995, 1996. So it has to be the old Prolene®, and we started our publication with presentation these materials. Now, we offered the stability, the elasticity, the subsequent adhering force, all parameters not

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very familiar to surgeons, but we have learned it.

Q. You've told me earlier today that when you conducted an animal study for Ethicon, that Ethicon would send to you the mesh that you required.

Is that fair?

A. I would just change some words. We made some studies and we were supported by Ethicon. It's only maybe one or two where you can say we did a study for Ethicon because they are interested in.

Q. Fair.

A. So just to correct this.

Q. And I appreciate the correction. And I'll ask it better.

When you conducted animal studies supported by Ethicon, Ethicon supplied you with the mesh that you required for that study?

A. Yes.

Q. How are you confident that the mesh that you used in all of the studies where you reference Prolene® mesh is what you

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describe as old Prolene® mesh?

A. First of all, I rely -- first of all, from the time period because we got most of these materials, the Prolene® materials before 1998, and we did some images at that time of the textile and we -- in some of the publications, you see that we give an overview of the textiles so the surgeon can understand. And you have this typical configuration of the Prolene®.

Meanwhile, I'm not sure -- it could have been Amos, but I'm not sure -- no, I'm sure that the Ethicon -- that we got Prolene® -- the old Prolene® from Ethicon.

Q. Why are you sure?

A. Because of the images and because of the time frame when we got these materials. We started in 1995 with the first Prolene® mesh implantation.

Q. Dr. Klinge --

A. 1994.

Q. -- if you're doing a study comparing the meshes that are used in hernia repair, wouldn't it be appropriate to use a

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mesh that's actually used in hernia repair when you're doing a study?

MR. ANDERSON: Objection to form.

THE WITNESS: So the question is why we took Prolene® and not the Marlex.

QUESTIONS BY MR. THOMAS:

Q. No, not the question.

A. Okay.

Q. At a certain time in the '90s, old Prolene® was not used for hernia surgery anymore, you know that?

A. Uh-huh.

Q. You continued to do studies comparing Prolene® to other meshes used in hernia surgery, correct?

A. The --

Q. And the question is why would you use a mesh no longer used in hernia repair for studies comparing meshes used in hernia repair?

A. The main point I want to stress is that we never have tried to be a tester of

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a medical device or a mesh that has been used somewhere. Our purpose was to understand what happens there and, therefore, we took as a comparison a mesh, a heavy-weight mesh and Prolene® is the heaviest mesh, the mesh where we know that it is -- yeah, the small pore, heavy-weight meshes that makes these differences and, therefore, for comparison, we took this mesh and it was -- we were very happy that Ethicon provided this heavy-weight mesh for our research and for our comparisons. And if you look to all of these studies, you see that there is always for comparison a heavy-weight mesh.

You only have one exception where we took the Marlex mesh, but usually the heavy-weight Prolene® mesh is a high-risk device for inflammation and fibrosis that was the Prolene®.

Because for our study, it was an excellent choice.

Q. Well, isn't a PVDF mesh twice as heavy as Prolene®?

A. That is, of course, everyone

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who knows some chemical textbooks knows that the specific weight of the PVDF is double as high as the polypropylene and that leads me to start or to point out that weight, per se, is not relevant alone. That is not sufficient because you can create with a lighter polypropylene, small pore meshes with an awful behavior. There are some studies clearly showing this, and you can produce some heavy-weight meshes with large pores of PVDF with an excellent behavior.

So the discussion about the specific weight and the weight of meshes as an indicator of the biocapability or whatever, it is misleading and --

Q. Well, early in your research, heavy-weight was a real indication of an unsafe mesh, wasn't it?

A. Again, you have to go to the history. The first -- the first publications it was called light-weight, large pore and small pore, heavy-weight. These -- the combination of these words. In the '90s, we haven't been able to have a good measurement

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of pores. There has been various measurements of pores, but it was -- we didn't have a sufficient understanding of this. And, therefore, because of these difficulties, the terminology was reduced and it was mainly reduced by the marketing from Ethicon because they found it easier to transfer the message light-weight versus heavy-weight and, therefore, the posters are indicating and stressing that VYPRO, ULTRAPRO™ is a light-weight version. Within some limitation that is true, but for the overall estimate of these meshes, that is not sufficient, the weight.

Q. And just to be clear, when your research started, you were very concerned about the weight of a mesh, correct?

A. We were concerned about the overengineering. As you remember, the first question where how strong should a mesh be and that was our concern and then we made the material reduction. And if you compare it to different polypropylene and made a material reduction, you get a lighter weight. You get

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larger pores, less risk. But this was truncated to this weight.

Q. Is it fair to understand, Doctor, that the state of your research today is that weight of the mesh alone is not an indicator of its safety?

A. If you -- as I said, if you compare same polymers, the weight as an indicator of less material can mean that the pores are enlarged and that you may have a better outcome, but as from the beginning, it's the pore size that is decisive.

Q. Is it fair to understand, Doctor, that the state of your research today is that weight of the mesh alone is not an indicator of its safety?

A. Is not a sufficient -- yeah, is not a sufficient indicator of the safety, yes.

Q. Thank you.

Do you know whether you have ever tested the second generation Prolene® mesh?

A. I do not recall to have done

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it.
Q. As you sit here today, do you know the differences between the old Prolene® mesh and the next generation 6 mil Prolene® hernia mesh?
A. The pore size gets smaller, I guess, and the second generation of the Prolene® mesh is -- I suppose it is done because the old Prolene® mesh has an extreme anisotropic behavior. So extreme differences in the strengths in the horizontal and vertical direction and, therefore, in the next version of the Prolene®, there is some more complex link -- cross-linking of the filaments.
Q. What do you base that on?
A. On the images. I've seen some images, but maybe there are so many modifications I'm mixed up, but --
Q. Are you -- I am sorry.
MR. ANDERSON: Go ahead.
THE WITNESS: No.
QUESTIONS BY MR. THOMAS:
Q. Are you concluding from your

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review of the images the reasons for the change or have you read somewhere why Ethicon made the change in the mesh?
A. I just concluded it. I never read -- I never got a document where I can see the reason why they changed it or whether they made some investigations to see what are the consequences. I never see something about it.
Q. Do you know how long the second generation 6-mil Prolene® mesh was used in the treatment of hernia repair?
A. No.
Q. Do you know whether the 6-mil second generation Prolene® mesh was used at the hospital at your university for the treatment of hernia repair?
A. I didn't see a document stating this, but I know with the development of VYPRO and the launch of VYPRO and the ability to use VYPRO we didn't use -- in the surgical department, we didn't use this type of mesh any longer. Except for some indications, thoracic wall.

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Q. I am sorry, for --
A. But not for the treatment of hernia. We didn't use it for the treatment of hernia.
Q. Okay. Was VYPRO the only mesh you used for the treatment of hernia repair?
A. In the time period when it was developed, this was our mesh that we used there.
Q. I understand.
A. Later on it was replaced by ULTRAPRO™.
Q. Okay. Other than VYPRO I at this time, did the hospital at the university use any other kind of mesh?
A. Our surgical department, my colleagues and me, we didn't use others. There is a -- there are others -- there are other departments, plastic surgery, I don't know whether they use different materials. We once tried to get a Mersilene mesh there because Professor Stupper has visited our department and performed an operation there and, therefore, for him we tried or we got a

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Mersilene mesh so we had available some other meshes there.
We had some guys showing to us laparoscopic incisional hernia repair and, therefore, for this purpose ePTFE has been used, for example.
The common mesh was VYPRO and later on ULTRAPRO™, but there has been some exceptional others.
Q. Do you know whether Prolene® 6-mil second generation mesh was ever used at your hospital for the treatment of hernia repair?
A. I don't know it.
The old mesh?
Q. No.
A. 6-mil you're talking of Prolene® and new mesh?
Q. There's a second generation 6-mil hernia mesh, you know that?
A. Sorry, I didn't get --
Q. There's a first generation, the original Prolene® mesh which was 6-mil, the second generation was the change in pore

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design and it's a 6-mil mesh also, correct?
A. Uh-huh.
Q. And there's a third Prolene® mesh, correct?
A. Yes. With a smaller 5-mil.
Q. And when we say 5-mil, that's a smaller fiber, correct?
A. Yes.
Q. And there's a change in pore design as well or do you know?
A. I know that there are differences in the pore design, but I cannot recollect this image now precisely. You have to show me.
Q. Well, it's in your report as you know -- we'll come back to that.
Do you know whether in your testing of meshes whether you ever tested the 5-mil Prolene® hernia mesh?
A. To be sure, it would be nice if you can demonstrate an image of the -- or this Excel grid where you see --
Q. It's in your report, Doctor.
A. -- the Prolene® II --

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MR. ANDERSON: It may be in his report, but he still has a right to look at something so he's just asking if he can see it.
MR. THOMAS: Page 77.
MR. ANDERSON: That's fine. He's just asking to see it. Is there something wrong with that?
MR. THOMAS: Please, Ben.
MR. ANDERSON: Well, I'm asking you.
THE WITNESS: So this is Prolene® hernia system. This is the old Prolene®, of course. Marlex, of course. The 5-mil -- I don't recall that we tested this in the histologic.
QUESTIONS BY MR. THOMAS:
Q. How would you know if you tested it when you did your studies?
Did you actually select the mesh and implant it in the rats so you would know what it was or did somebody else do that for you?
A. No, I --

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MR. ANDERSON: From '94 to 2000?
MR. THOMAS: At any time.
MR. ANDERSON: At any time.
QUESTIONS BY MR. THOMAS:
Q. You already told me you conducted your own rat studies and made your own implantation in the '90s, but you also told me there are times when the others did the study and implanted the mesh in the rats.
A. Yes. So in the first years, I did a lot of these operations myself, later on I participated at many operations, but to the protocol of all these implantations, it was clear and I required it that we made some images of the textile. So because if you made a presentation and if you made a publication, what we have learned is that it is essential at the beginning to show the mesh and to show the specifics of this mesh. Not to get in trouble that you have another modification. And, therefore, I have seen the images of all these meshes there and I cannot recall that we made experiments with

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this type of Prolene®.
Q. Why not?
MR. ANDERSON: Why can't he recall?
QUESTIONS BY MR. THOMAS:
Q. No.
Why didn't you do tests on this 5-mil hernia mesh?
A. Why didn't we do it?
Q. Yes.
A. Because we were busy and what is the scientific -- can you give me a scientific reason for looking at this?
Q. Do you know whether it's still used today in hernia repair?
A. Maybe, but as I told you, we are not tester of a medical device, whether it works or not. We want to know how it happens, what is the functional impact.
Q. Wouldn't you want to know the tissue reaction to the 5-mil hernia mesh?
A. In comparison to what? To 6-mil?
Q. Or whatever other standard you

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want to measure it to. Don't you want to figure out how it performs like you had measured all of the other meshes?

MR. ANDERSON: Objection to the form.

Go ahead.

THE WITNESS: I'm not -- the major interest is not to see whether a specific device performs differently to another. A question can be the change of 6-mil to 5-mil, what is the impact of the tissue reaction. The reduction of the pore size from -- I don't want to give a figure. It's impossible to give one specific figure, but the change of the textile structure, what is the impact of the tissue generation. This is a question I think a manufacturer should answer this.

The scientific question would be the dependency of the tissue reaction from the size of the filament and then we have to construct five,

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six different modifications, different filament size and then look to the tissue reaction. That would be a nice experiment and you can do it if you have the resources and the money, the people and the time. Yeah, but just to look what happens to a specific, there are more than 200 meshes on the market. We are not able to do so.

Q. Is it your best recollection that the only Ethicon polypropylene mesh that you've tested for hernia repair is the first generation 6-mil mesh?

A. So far I recall, all of the images from the textiles we have, yes.

Q. When you received mesh from Ethicon for the studies that you conduct, you've told me that it comes in a special package and marked experimental use.

Is that fair?

A. They come in a special package, yes.

Q. What size are they?

A. What size?

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Q. Yes.

A. It is a plastic box like this. It depends. For the rat studies and we ask for 2.5 to 3.5 centimeters, they're already cut. They are enclosed in a plastic sheet. They are enclosed in a metallic film there and they're included in another plastic sheet there and then 24 -- I think 24, 20 of these meshes are put together in a plastic box and then this plastic box was wrapped in a plastic sheet and then we got this one.

Q. Okay.

A. And then we got a list with a number CV something like this, some artificial number, and then --

Q. And who provides the mesh to you? Is it Norderstedt?

A. Norderstedt. Dr. Walthe, yeah. I think Dr. Walthe, he's preparing all this.

Q. Doctor, whenever you place an artificial implant in the human body, there is a chronic foreign body reaction for the rest of the patient's life with an implant, isn't there?

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A. That is correct.

Q. And that's whether it's a hip implant or a knee implant or a mesh implant?

A. That is correct.

Q. And you learned that in medical school, didn't you?

A. This general statement, yeah, we learned it in medical school.

Q. And any time that you put mesh in a patient for hernia repair, you told the patient that I'm putting an implant in you, you need to understand that there will be a long-term, chronic foreign body reaction for the rest of your life?

A. No, that is not the issue. Because --

Q. Did you tell patients that?

MR. ANDERSON: Excuse me, let him finish his answer.

Finish your answer.

THE WITNESS: It is not the appearance of a chronic body -- a chronic foreign body reaction which can be defined in pathology lifelong.

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This is not relevant. This is not the issue that is to be discussed with a patient. The patient is interested in what are the consequences of the chronic inflammatory foreign body reaction. So what is the risk for -- from the implant. In our scientific discussions, we know that it is because of the chronic foreign body reaction, but I think it is not valuable information for the patient that there is some chronic foreign body reaction and there are some macrophages, but he has to know that there is a chronic wound which means a lifelong risk for infection that can occur after some years, for chronic pain and that we -- might be impossible to prevent a occurrence at any case.

Those are the things that we have to discuss with a patient.

QUESTIONS BY MR. THOMAS:

Q. So you tell a patient when

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you're installing a mesh for hernia repair that there's a lifelong risk for infection?

A. That there is a lifelong -- permanent mesh material there and that there is a possible risk lifelong for late infections, late onset on chronic pain. Yeah, we tell it. And that is difficult to remove this. This is the other point.

Q. And there is a risk of chronic pain by the implantation of that mesh?

A. Yes. Of course, it is one of the major issues in hernia surgery there are rates of up to 40 percent of chronic pain in patients after every hernia repair, but 80, 90 percent meanwhile are done with meshes.

Q. And you tell them there's a risk of recurrence?

A. Yes, of course.

Q. And you tell your patients all of these things when you were doing surgery so that the patient could make a judgment in consultation with you about whether they wanted to have this procedure?

A. It's an interaction. It's an

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interaction that the wishes of the patient. It is -- he relies a little bit on my experience of the arguments that are behind and then, yeah, you find the best solution for the patient together. I think it is very difficult to separate this one that only the patient decides, no, he's not able to decide.

Q. It's a conversation that the patient and the doctor have together and hopefully the two of you together --

A. Yes.

Q. -- can make that decision.

A. Yeah. I think that is what you expect and me expect that you find together the solution, best solution for you.

Q. That's why you need a doctor to help you counsel through these kinds of issues?

Strike that.

Ultimately, it's the patient's call, correct?

A. What?

Q. Ultimately, it's the patient's decision whether to go through with the

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surgery, you agree with that?

A. To -- whether he will -- he has to agree that he wants to have this treatment. That is a final decision by the patient, yeah.

Q. And the patient has to determine whether the benefits of the surgery outweigh the risks that you've explained to them?

A. If you define this as the way to make up the decision that he finds this balance of disadvantages and advantages, yes, that is.

Q. When you talked about infection a minute ago, you talked about infections that occur later in life that might be mesh-related.

Tell me what you mean by that. How can you have infections from mesh later in life that are mesh-related?

A. The most important experience that we have got while we are looking to the explants from Professor Klosterhalfen, and when we look when this was sent to the -- or

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when this was explanted, this was explanted because of infection two years after the operation. We -- in the late '90s, we have seen the first report from the UK where someone has described this late onset infection of the operation and he always describe this latency of more than a year. There has been a big review from the US, from, I think, what age -- starting with age, but they, again, said that infection occurs with a long delay of two years.

So in contrast to the early infection that occurs immediately in the first weeks after the index operation, there can be some infections manifesting after two years, 50 years, with a foreign body with an implant. So this is an experience and, therefore, it is not so that every patient has to face this complication, but there is a lifelong risk and if you're 80 years old, the lifelong risk fortunately is small, is shorter, but if you're 20 years old and you expect that this implant has to work there for another 70 years, of course, the risk is

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higher to experience an infection than in an old patient. And that has to be part of the discussion, the risk evaluation for the patient.

Q. As a doctor, hernia surgeon, you had that discussion with the patient?

A. Yes.

Q. Now, what's the background risk for a surgical site infection for a hernia?

A. The background?

Q. What's the general risk of infection for a hernia surgeon?

A. A hernia surgeon? You have to differentiate what type of hernia.

So incisional hernia is a completely different case as groin hernia. You always have the combination by some skin bacteria that is the early surgical site infection. You can have an infection due to erosion of some bowels, for example, that is a problem when you place the mesh in the abdominal cavity. You can have a secondary invasion of bacteria sitting or going to the implant and being for some immunological

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reasons activated there. Yeah, that may be. And necrosis, if you made an operation where a lot of tissue is going to be ischemic and you have a lot of these damaged tissue around and you have an increased risk if you have a history of a past infection, then you have an increased risk.

If you take some drugs, immunosuppression after transplantation, you have an increased risk. If you have diabetes, you have an increased risk.

Q. What's the risk of a surgical site infection for an incisional hernia?

A. Incisional hernia, it is -- in very many studies, it is about 10 to 15 percent.

Q. What's the risk of the surgical site infection from groin surgery?

A. It depends which study you are looking at. If you are really making a follow-up for three weeks, then you're in the range from 3 to 5 percent. If you're looking to day surgery leaving the patient in the evening and asking whether he has an

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infection, then you have perfect numbers, very close to zero percent. So there is always this variation.

Q. Do you distinguish between surgical site infections and these latent infections?

A. Yes, I, personally, I do so. Because it is another time period when it occurs and it is another challenge for the surgeon if a patient is coming two years after an operation with a swelling here or sometimes it is a -- just a finding by chance that there is a tumor or so and then it is a late onset bacterial infection, it is always a challenge.

Q. Surgical site infections are a risk of any surgery, aren't they?

A. There is no surgery with zero surgical site infection risk, that is true.

Q. Do you have a number of a rate of infections, latent infections, that you would attach to incisional hernias?

A. Latent infections in incisional hernias. There is a very limited number of

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reports of systemic reports, long-term reports and that is the importance of the registries because you cannot imagine a randomized control trial looking for 50 years to 1,000 patients. You only get it from registries.

And there from the US, I think, the best data are there where they looked to all patients with incisional hernia and looked to the explants. The reason for explantation is given in about three percent of the patients with incisional hernia in this study.

Q. Okay. And for those explants that are removed because of latent infections in the three percent that you just described, are you able to determine the source of the infection from the explant?

A. There are reports where someone has made microbiological investigation and he was successful to identify the germ there. It is possible to do so.

Q. What I'm talking about, just to make it a little bit clear, you've talked

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about secondary infections. It's true that a person can develop an infection in one part of the body that can migrate to the implant and have an infection at the implant.

Is that true?

A. To my knowledge, we believe in this conception. That is the reason that, for example, cardiac valves, you have to make a protection of antibiotics if you have -- if you receive a colonoscopy because we believe that these bacteria are going to the implant and obviously there has been some reports of it.

Q. There's --

MR. ANDERSON: Wait, are you through?

THE WITNESS: Yes.

QUESTIONS BY MR. THOMAS:

Q. There's a risk, for example, of a heart valve if a person has a procedure where a heart valve's implanted, they can develop an infection in another part of their body, it can migrate to the heart valve and can be a real problem, even tragic death,

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correct?

A. So --

Q. Is that yes?

A. There is a current -- yes, there is a current knowledge that there you have a migration of the germs to the implant, the secondary.

Q. And that can happen whether it's a knee implant or a hip implant or a heart valve, correct?

A. In principle, I totally agree, but I don't have any specific data showing what is the risk. It depends from the age of the comorbidities and all of these things. In principle, there is a risk.

Q. You're not trained as an infectious disease doctor, are you?

A. Just by my work and facing the problems with patient with surgical site infection and, as you stated already, my surgery as well, they made -- I suffered from some surgical site infections.

Q. You, yourself, or your patients?

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A. No, I suffered from my patients, yes.

Q. Well, when you have surgical site infections, do you refer them to an infectious disease doctor?

A. No, in Germany, we didn't do so. It depends from the structure of the hospital whether you need this additional skill or not.

Q. And if you're unable to treat the surgical site infection with your own skills, certainly you have that discipline available to you to consult with.

Is that fair?

MR. ANDERSON: Objection to form. Discipline was --

THE WITNESS: I didn't get --

QUESTIONS BY MR. THOMAS:

Q. If you needed an infectious disease doctor for an especially complicated infection, you certainly could find one if you needed one, couldn't you?

A. I never made the experience. We're at the university. We are at the

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maximum. We're at the upper level of this and other people send us patients that we treat them --

Q. Okay.

A. -- and they fail to do so and there was no other hospital where we can send --

Q. I see.

A. -- the patients to. So I didn't have the experience whom to ask. In the field of visceral surgery and complication of meshes, so I --

Q. Does the -- I am sorry.

A. Yeah, I cannot give you any statement of this.

Q. Does -- when you were practicing surgery -- and you haven't done surgery since 2006?

A. Yes.

Q. When you were practicing surgery, did your hospital have an infectious disease doctor on staff?

A. In the hospital, there is an institute for microbiology that when we want

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to have some investigations, they can do it. We have a doctor who is responsible for infection in the hospital. He's doing some statistics there and some training for cleaning the hands, washing the hands and so. He's visiting the intensive care unit, looking to some bacteria there.

But it is not -- it has not been part of the daily practice that he advises surgeons what to do.

Q. Let me ask the question this way.

Is there -- while you were practicing surgery, was there a doctor at the hospital where you practiced that had a specialty in treating patients with infectious disease?

A. Surgical infectious disease?

Q. Yes.

A. No. We did it.

MR. THOMAS: I need to take a break.

MR. ANDERSON: Okay.

(Off the record at 4:50 p.m.)

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QUESTIONS BY MR. THOMAS:

Q. Doctor, I spent a lot of time talking to Dr. Klosterhalfen this weekend about the collection of explants that he has, both hernia explants and pelvic floor explants.

What kind of collection does your hospital maintain in terms of explants?

A. The explants I have access to that are explants that has been explanted by my colleagues from the surgical department, only from the surgical department, and they are -- and they made an explantation, they send it to our lab and then I get informed and then we place it on stock for the next time.

Q. What do you mean, place --

A. We store it.

Q. Okay. You place it in formalin?

A. In formalin, yeah.

And there may be other explants that may go to the Institute for Pathology, but I have no access to this.

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Q. So when your surgical colleagues explant a mesh, it doesn't immediately go to pathology for analysis?

A. No. There is -- there is no -- the pathology is not really interested in looking to the pathology of these mesh materials, but we are interested in, we made investigations and so this is sent to our lab.

Q. Okay. What are the occasions when an explant goes to the Institute of Pathology for review? Why would that happen?

A. An explant may be from the department for gynecology. They will send it to the pathology or some other department. They may send it to the department for pathology, but my colleagues and myself at that time when I explant mesh materials, we are collecting these materials in our lab and for -- because we are interested in analysis, we are interested in specific questions and, therefore, we make this investigation. We don't want to have a standard evaluation of mesh materials.

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Q. Okay. Are all of the explants in the collection that you maintain at the hospital hernia explants?
A. Explants that have been explanted from patients with hernia and I always try to get the documents from the OR, what happens there and the medical records of these patients.
Q. And how many hernia explants do you have?
A. It has been around 600 when we --
Q. And how long have you been collecting hernia explants?
A. We really start to look for this, it was in parallel to the increased use of the mesh materials and this starts in about 2000. In the years before, it was -- meshes were rarely used. So it was rarely the occasion to get a mesh there, but meanwhile, yeah, 30, 40 percent of the patients that you made an operation for recurrent hernia already has some sort of meshes in the --

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Q. Is it standard practice in your department when a surgeon explants a hernia mesh that they provide it to you?
A. It is -- it is a very visual thinking of all participants and fortunately most of my colleagues are involved somehow in the scientific work of meshes and, therefore, most of the colleagues have been a big interest to send me their explanted mesh materials.
Q. So it's a voluntary decision on the surgeon as opposed to a procedure of the hospital about whether to send you the mesh?
A. No, it's voluntary by the surgeon whether to throw it away or send it to the lab, yes.
Q. And when you receive the mesh, you collect whatever medical records that you can associated with the mesh?
A. Yes.
Q. Do you have a form that you use to detail the information for each of the explants?
A. The paper for documentation of

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the parameters, it is always defined for a specific question. I don't build up a registry with some basic data where I put in some maybe or likely irrelevant information in it. So when I want to make a study, I choose some explants and then I decide if I want to study this and I need this parameter for controlling the conditions.
Q. Who has access to your collection of explants?
A. Every member -- in principle, every employee from the surgical department so.
Q. Do you control who has access to the explants?
A. No.
Q. So anyone can go in and check one out?
A. I know who is doing research. It is -- no one is going there and taking them and so you need some specific question to do so and if someone has a question, then yeah, likely he will communicate this and then he can take ten of these explants to do

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some research or if he wants to look.
Q. When Dr. Klosterhalfen left the university and went to Düren, did he take any explants with him?
A. I don't know. Maybe he took some ex -- he -- maybe he took the explants that he collected in the Institute for Pathology until 2003 that he took this number of explants to Düren maybe.
Q. Okay. You know that Dr. Klosterhalfen collected explants while he was at the university, correct?
A. Yes. On several occasions on the presentations we said to the audience, if you have an explant, feel free, no cost, feel free to submit it to Professor Klosterhalfen in Düren or Aachen. He will be very happy about it. So it was a pleasure for me to announce this.
Q. The explants collected by Dr. Klosterhalfen while he was at the Institute of Pathology are no longer at the university, are they?
A. I don't know.

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Q. Okay. Okay. Do you have access to Dr. Klosterhalfen's collection of explants?
A. Access in the meaning that he shares his data, his evaluation, yes.
Q. Do you have access that you could go over and remove some of his explants for your own testing?
A. Remove? So if I want to see some and make some further investigations, of course, I don't see any problems that we can do so.
Q. You typically don't --
A. I never had the idea to go there and to remove something, no.
Q. Okay. The research you do is on your own collection of explants, is that fair?
MR. ANDERSON: Objection.
THE WITNESS: We have a very close collaboration still there. It's depending from the time point, but as I saw at the beginning this research program with the European Union, that

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was done because we need a lot of staining there and I asked him whether it's possible to do this at his department, with his machines because they're better than what we have in our lab and so, therefore, I brought him the box and the staining was done at his facility. So it's no problem. It's 30 kilometers.
Q. Has the hospital -- strike that.
Over the last ten years, has the hospital where you currently work used mesh for the treatment of pelvic organ prolapse?
A. As I know from the discussions with -- we have a center for treatment of incontinent patients and we had several discussions and we have several joint projects and scientific projects with the members of these incontinent center and, therefore, yes, in the discussion, they said they used these, they used meshes. Not as a first line indication, but in some severe

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recurrent patients where a mesh-free device has failed there, they choose to make a reenforcement of tissues with the help of textiles and since one year, two year they change completely to PVDF.
Q. Okay. Is that for both -- I asked the question was pelvic organ prolapse.
Does your hospital use mesh for the treatment of pelvic organ prolapse?
A. Yes. In these cases.
Q. What do you mean "these cases"?
MR. ANDERSON: The ones he just told you about. He was answering your question about pelvic organ prolapse.
THE WITNESS: Not a first-line therapy, only in recurrent and --
QUESTIONS BY MR. THOMAS:
Q. I understand.
A. -- in some selected patients.
Q. Now, does your hospital use mesh for the treatment of stress urinary incontinence?
A. Yes.
Q. And you told me a minute ago

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that they -- two years ago they changed completely to PVDF.
Is that for both procedures?
A. My impression within the last two years. It is not two years ago sharp time point, but within the last two years. Actually, they are using PVDF for both indications because I assume -- within the past three years, we have increasing conversation about our experiences. We have made a lot of discussions and meetings with our scientific projects. We have been going to the animal facilities, to the anatomy to look for all of this and, meanwhile, they're convinced that PVDF is better.
Q. How long have you had these conversations with the Center for Treatment of Incontinence?
A. The first project started in 2007, 2008.
Q. And tell me how that happened.
A. It was a -- it was a project together with the FEG as a small medium enterprise, together with the Center for

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Incontinence and together with me and together with Professor Muhl.
Q. Is that Mullen?
A. Muhl. Muhl from the -- from our pore -- you see Professor Muhl from Monday.
Q. Okay. It's the engineer --
A. The engineer, yeah.
So there has been a project for the development of -- yeah, for uses of mesh in the pelvic floor area. And there has been another for finding a good or to create an anchor system or to study anchor systems for the use for mini slings and, yeah, that these has been the major activities.
Q. What kind of mesh is used for the treatment of stress urinary incontinence in your hospital now?
MR. ANDERSON: Objection. Asked and answered.
Go ahead.
THE WITNESS: I don't know exactly.

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QUESTIONS BY MR. THOMAS:
Q. In your discussions with the Center for Treatment of Incontinence and your gynecologic department, have you ever requested that they give to you explant or tissue samples from their patients who have had mesh removed from pelvic organ prolapse?
A. Not -- definitely not -- no.
Q. Why not?
A. No. Because I'm rather busy to do so, so a collection of all of these materials it takes a lot of time to have a systemic analysis and I'm busy enough to investigate all of these others, to make up the consequence -- the competition to Bernd Klosterhalfen with all of his explants, no. But maybe it's a good idea to tell them they shall send it to Bernd.
Q. Do you know whether they send them to anybody?
A. I guess they send it to the Institute of Pathology in our university.
Q. But you're guessing at this point?

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A. I'm guessing.
Q. They may be throwing it away?
A. Yeah.
Q. You think that's likely they're throwing the explants away?
A. I wouldn't be very surprised.
Q. Okay. So as far as you know, the explants for both pelvic organ prolapse and stress urinary incontinence are likely being thrown away or being sent to the Institute of Pathology?
A. I would agree to this statement, yeah.
Q. You don't want access to those because -- "those" being -- strike that.
You don't want access to the explants for pelvic organ prolapse or stress urinary incontinence because your hernia explant collection is keeping you plenty busy?
A. No, that is not correct. I deeply want to have access to this, but it has an inferior priority for what I'm doing there. It would be very -- I would be very

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happy if we have the facilities to collect all of these textile implants and to have a scientific investigation and evaluation of this. Yeah, it would be very helpful for all of us.
Q. But at least today you haven't done that?
A. I haven't done what, building up this institute?
Q. Collected explants from pelvic organ prolapse or stress urinary incontinence?
A. That, I didn't done up to now.
Q. Okay. Do you know what a Burch colposuspension is?
A. I've heard this phrase, yeah.
Q. What is it?
A. It's a suture repair.
Q. Suture repair of what?
A. Of pelvic floor prolapse.
Q. Okay. And where do you get your understanding of the Burch colposuspension as a suture repair of pelvic floor prolapse?

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A. I have read from the literature.
Q. Okay. What literature -- strike that.
Can you describe for me how a Burch colposuspension works?
MR. ANDERSON: Objection. Counsel, you know we're not having him offer any opinions on the Burch colposuspension.
MR. THOMAS: I'm just asking if he knows.
THE WITNESS: I know that I read it. I know that I did understand it, but I cannot recollect this phrase of this textbook where it works.
QUESTIONS BY MR. THOMAS:
Q. You said you understood it.
Other than being a suture repair of a pelvic floor prolapse, what do you understand it to be?
Is that the extent of your knowledge?
A. Same thing. So we can together

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go through the textbook and then I'm able to explain you what is done by this.
Q. Doctor, do you know the primary method of treatment of stress urinary incontinence before the use of mesh?
MR. ANDERSON: Objection. All of these questions about implantation or SUI.
Go ahead, Doctor.
THE WITNESS: There has been -- I know there has been some attempts to have some -- to improve the -- to the function by placing some tissue approximated by sutures there. There has been used some fistular slings in the beginning of the '90s, first attempts to make a sling-like repair and then later on it is replaced by artificial slings.
QUESTIONS BY MR. THOMAS:
Q. Are you familiar with randomized control trials comparing the use of mesh to other alternative procedures for the treatment of stress urinary incontinence?

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A. I noticed the results. I had to look to some meta-analysis mainly from the UK from the NICE where they made up this evaluation of these comparative studies of the various approaches. It's a very thick document and there are these comparisons where -- have been there.
Q. Is that the extent of your review of the literature of randomized control trials comparing the use of mesh to other traditional repairs for the treatment of stress urinary incontinence?
A. No, it's not limited to this, but the meta-analysis published in the UK, that gives a very good overview that, of course, every week, every month there is published new studies, new reports and I try to get informed about the recent development in this field.
Q. What is NICE?
A. NICE, it's the British -- it's the British office that is reviewing the -- or that has to be -- that has to do something with the -- controlling the efficiency of

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some therapies. They're giving advices to the patients, to the doctors, and they try to define some standards and guidelines.
Q. And the --
A. I don't know the abbreviation where it's specifically.
Q. That's fine.
And what are the standards and guidelines for?
MR. ANDERSON: Objection. If you know.
THE WITNESS: Standards and guidelines they tried to give a -- to give an advice to patients how to treat a standard patient in a standard way so, therefore, many, many surgical and other societies tried to define some guidelines how to treat a patient in a specific situation with what sort of therapy so the surgeon can ask these guidelines and can confirm whether he treats the patient in the best way that is in the moment advice by the literature and the officials.

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That is maybe the function of the guidelines.

It is not able to give a specific advice for the treatment in a specific patient.

QUESTIONS BY MR. THOMAS:

Q. In your experience, do doctors consult the NICE guidelines in connection with rendering care and treatment to patients?

MR. ANDERSON: Objection.

THE WITNESS: I know some investigations from guidelines from the Dutch where they changed the guidelines and then later on asked the doctors where they follow the new guidelines, yes or not, the result was rather disappointing. So I'm not sure whether the guidelines published by NICE or someone else really changed the attitude of the doctors, but, of course, these guidelines reflect the knowledge that most of the doctors will share.

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QUESTIONS BY MR. THOMAS:

Q. Is it your understanding the NICE guidelines attempt to reflect the best judgment of the experts in the field about the standard source of treatment for a patient who is suffering from a certain condition?

A. It's even more. They don't -- attempt -- good guidelines don't attempt to reflect only the meaning of the expert, but they're collecting and providing a meta-analysis of the data and then together with the experts, they together try to define what can be the best treatment for the patient, yes.

Q. You've mentioned this is a UK publication.

You obviously have consulted it here in Germany.

Do you know if others in the EU consult the NICE guidelines?

A. I don't know. But we have German guidelines as well for the treatment of incontinence, and interestingly in 2003,

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2004, the first version, the sling repair was advocated as first treatment and meanwhile it is restricted to the elderly patient.

So there is some dynamic change in all of these guidelines, but they reflect the actual state of the opinions.

Q. What organization in Germany provides guidelines similar to those that you've described are offered by NICE?

A. It is called the AWMF. It is placed at the server in Dusseldorf.

Q. What is it?

A. It is a joint -- a community of several medical societies or all medical societies, they agreed to work together in this AWMF and they offered a lot of guidelines for the treatment of cancer, for the treatment of incontinence, for the treatment of cirrhosis, and so forth, for all of these things and this is on the internet and you have various levels of evidence and, yeah, everyone can go to the internet and have a look to it. This is our German platform.

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Q. Okay. So you went and consulted the NICE guidelines for the treatment of stress urinary incontinence; is that correct?

MR. ANDERSON: Objection to form. Misstates testimony.

Go ahead.

THE WITNESS: To get an overview what happened there, I try to look to every guidelines and, therefore, in PubMed, I place there the key words, guidelines and mesh and incontinence and so one of the guidelines I saw there was this one from the UK, and I think I liked it very much because it seems to be very accurate at that time. It's some years old, again, but there are a lot of other summaries of the knowledges and the randomized controlled trials that you referred to.

QUESTIONS BY MR. THOMAS:

Q. Before you did this PubMed search that you've just described, had you

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ever determined the positions of NICE or the AWMF on the care and treatment of stress urinary incontinence?

MR. ANDERSON: Objection to form.

THE WITNESS: I didn't get the question.

QUESTIONS BY MR. THOMAS:

Q. You just described for me two organizations that you consulted in your work in this case.

A. No, not in this case. Sorry.

Q. Okay. I am sorry, I misunderstood.

A. So I started to think of this very intensely. I went to look to the literature when we made our publication for medical device dealing with the slings.

Q. Back in 2007?

A. Huh?

Q. Back in 2007?

A. Yeah. That was the first time that we looked regularly to the literature in this. But, again, this is another reason to

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have a look to it, but meanwhile, I'm invited by many gynecological societies. So it is a hot topic, mesh in urogynecology and, therefore, I try to get -- to get or to keep informed.

Q. Okay. And where do you go to keep yourself informed on the hot topic of mesh in urogynecology?

A. Apart from the communication at the conferences or the meetings, for me, the best indicator of that is a hot topic is if you count the publications in MEDLINE®, if you place there the topic mesh, almost a third of it, of the recent publication of the last year are dealing with mesh in the pelvic floor area. So it is increasingly discussed and if I look to all of the publications that included some references of my work, I get who is interested including a citation of our work, then I see again there is a lot of gynecologic, urologic mesh papers there. So that is the reason.

Q. Now, in the United States, there are professional societies of hernia

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surgeons and of gynecologists and urogynecologists and urologists and each of those organizations has journals that they published.

You're aware of that?

A. Yes.

Q. In Germany, does the AWMF, is that a similar organization? Is that a professional society that has a journal?

A. No. No. I don't think that they have an own journal. They provided the internet platform so that everyone can have access to this.

Q. Okay. And is it government-sponsored?

A. I think so, yeah.

Q. Okay. So it's an organization of the German government?

A. I think so.

Q. Is it -- is the medical system in Germany, is it national health care?

A. We have a very complex medical system. The universities belong to the countries. The health system belongs to, I

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think, about 100 insurance companies, different insurance companies.

Q. And all I'm asking is whether the AWMF is part of the government that describes what procedures will be paid for and under what circumstances, do you --

A. No, it is not related --

Q. That's fine.

A. -- to any reimbursement.

Q. That's exactly what I'm asking.

A. Nothing about this. This is completely different. It's just the medical definition of appropriate therapies or best therapies.

Q. All right. Is there any other organization in Germany about which you're aware that identifies the appropriate therapies for different conditions such as the AWMF or the NICE?

A. There are several societies from the urologists and from the gynecologists in Germany as well, and they try to do -- to give some statements, but I'm not aware that they have provided guidelines

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in the quality of the UK. That is not available with them.

Q. Okay. So at least in your experience, the guidelines in the UK and the NICE guidelines are of superior quality to what's available from the German professional societies?

A. No, I wouldn't say that, but the -- I don't -- I don't want to focus on what the guidelines are saying. The most important thing for me is when you're looking to the guidelines from the NICE, if you look to the document of 100 pages or 200 pages there, you have a very good collection of the status of the publications and the references and a good structure of it, and they present the data very, very nice. That is what I'm -- what I appreciate very much when I look into these guidelines. That is the point. Not the point whether they are in favor of or -- I have read this as well, but this is influenced by the UK health system and so.

Q. Okay. Are there any

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organizations of the EU that put out guidelines about appropriate therapies for patients with certain conditions?

A. I don't know any -- I'm not aware that the EU, that any organization in the EU gives this. There are these international societies for the treatment of incontinence. There are the American societies for urology, gyne -- international societies and these together, they provided some advices to treat, yes.

Q. Did you consult --

A. But EU, no.

Q. Did you consult the physicians of the American Urogynecological Society on the use of mesh for stress urinary incontinence?

MR. ANDERSON: Objection.

THE WITNESS: I have read some statements. Whether it's this American society or whether it's another, I cannot recollect. Yeah, but there is a discussion, very intense discussion pro and con and

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very often a mixup of pelvic floor prolapse and incontinence and older and younger patients.

QUESTIONS BY MR. THOMAS:

Q. Do you distinguish between pelvic organ prolapse and stress urinary incontinence about the use of mesh to treat those conditions, whether it's visible or not?

MR. ANDERSON: Objection to form.

THE WITNESS: As I indicated this morning, I think it is not very helpful to make this differentiation, however, I made it because you made it.

QUESTIONS BY MR. THOMAS:

Q. Okay. But if I hadn't distinguished the two, you would treat them together; is that fair?

MR. ANDERSON: Objection. Form.

THE WITNESS: What?

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QUESTIONS BY MR. THOMAS:

Q. Do you consider the two conditions to be one?

MR. ANDERSON: Objection to form.

THE WITNESS: There are many, many, many differences. If you stick to the problem of mesh -- of textiles -- the use of textiles in the pelvic floor area, you have to differentiate the effect of flat meshes in a flat area and from the reaction to a sling-like material. That you have to -- that is from my point of view, there is a different reaction and different discussion about the functionality and tissue response and structural stability, different requirements to these things.

So for the evaluation of devices, for the development of devices, it may be not thus helpful to have this differentiation in

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incontinence and prolapse. It is not sufficient.
QUESTIONS BY MR. THOMAS:
Q. Okay. Let me understand your answer.
You said, "From my point of view, there is a different reaction and different discussion about the functionality and tissue response and structural stability, different requirement to these things."
Does that mean that you need to separate the two in order to understand them and the appropriate reaction to mesh?
MR. ANDERSON: By "the two," do you mean POP and SUI?
MR. THOMAS: Yes.
THE WITNESS: Can you please rephrase it?
QUESTIONS BY MR. THOMAS:
Q. Your answer to my question before you said, "From my point of view, there is a different reaction and different discussion about the functionality and tissue response and structural stability, different

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requirement to these things."
That was the answer you gave just a moment ago.
A. Yes.
Q. And what I'm trying to understand is whether the different reaction, different discussion relates to the differences between mesh used for the treatment of pelvic organ prolapse and mesh used for the treatment of stress urinary incontinence.
A. What I try to explain is if you're looking to prolapse, you can -- there are some -- as Petros who said that -- are you ready?
Q. Yes, I am.
A. So if you follow Petros, he said that prolapse can be treated with sling-like structures, five, six sling-like structures. Others said you need flat meshes in this area. So if you want to discuss the requirements to the textile for the use, it is impossible to say that we define the requirements for the textiles for prolapse,

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it is not sufficient. It depends on whether you want to make this reenforcement with flat meshes or by slings. And, therefore, the summarize, or the grouping, prolapse and mesh, that is not sufficient because you can -- you have to differentiate flat mesh and sling. For incontinence, it is more simple because so far I know there are only slings and no one is until now had to realize the idea to treat it with a mesh. So that is my problem to address this problem. And if you just want to differentiate prolapse and the requirements for prolapse, it is not sufficient from my point of view. You have to specify for what sort of treatment, for what sort of textile.
Q. Are you familiar with the European Association of Urology?
A. I've heard it. They publish, yeah.
Q. Have you looked at the European Association of Urology guidelines on urinary incontinence?
A. I have to look at my computer

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where I've stored --
MR. ANDERSON: You can look --
THE WITNESS: Mesh and pelvic floor is in MEDLINE®, I think it's about a thousand hits. And it's increasing. Every week it's going up. So it is -- for hernia, it's 12,000 hits. So it's almost impossible to -- you can read a lot, but to have it -- to keep it in mind is almost impossible.
QUESTIONS BY MR. THOMAS:
Q. Have you made an effort to determine a consensus among surgeons who use -- strike that.
Have you made an effort to determine a consensus of surgeons who treat stress urinary incontinence of the appropriate method to treat stress urinary incontinence?
MR. ANDERSON: Objection. Go ahead.
THE WITNESS: That is -- that is a -- the discussion we had during

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the past half a year was Dr. Liedl, with Professor Jager, with Professor Kirschner-Hermanns, the head of the Incontinence Society, yeah, that is the severe discussion to find an agreement and they all admit that there is a complete mixup of the patients, mixup of the diseases, mixup of the therapies so we're still looking for the best structure because many of these procedures work very well in many patients, but every surgeon and everyone knows considerably fatal rates there, and to identify which patient should have another treatment than the one that has been selected, it depends of the definition of its individual condition, and it is difficult to have a satisfying preoperative condition in these patients and, therefore, all of these guidelines are too unspecific.

QUESTIONS BY MR. THOMAS:

Q. Okay. Maybe my question wasn't

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very clear. What I was trying to determine from you, Doctor, is the extent to which you've undertaken to determine whether there is a consensus of surgeons who treat women with stress urinary incontinence about the appropriate method to treat stress urinary incontinence.

I appreciate the fact that you've had discussions with a number of people, but have you reached any conclusion in your own mind about whether there's a consensus or not on the appropriate method to treat stress urinary incontinence?

MR. ANDERSON: Objection. Outside of his expert report, what I'm going to ask him to do in this case. But answer his question.

THE WITNESS: What do you mean by "consensus"? There are, of course, some writings in the literature where they say, okay, a consensus is like this and this and this. This society is saying this consensus. If I remember all of the discussions that

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we have in Aachen with the urologists, gynecologists of different towns, no, there is no -- there is no agreement of the best therapy. The one made it transvaginal, transabdominal, with mesh, without mesh, first-line mesh, depends from the patient so, no, there is no consensus that you really can say that is a standard therapy for all patients. I don't know it.

QUESTIONS BY MR. THOMAS:

Q. Doctor, have you -- strike that.

Are you familiar with the rates of complications associated with the use of mesh for the treatment of stress urinary incontinence?

A. I have read a lot of these articles, but I have to admit meanwhile I'm not very interested in these figures, in these rates.

Q. Why not?

A. Huh?

Q. Why not?

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A. Because I don't think that it reflects the reality. It is usually done in hundred patients or 50 patients, you have a follow-up time which is maybe six months, maybe sometimes one year. And statistically all of these studies are underpowered. So they are helpful to detect whether there is the risk -- whether there is a risk, to demonstrate that there is a risk, they are helpful because in some patients you can find some risks.

To define whether they can really confirm the safety of a procedure, they are underpowered. You need at least 2,000 patients. You have to make a follow-up of five years, ten years, and that cannot be done, that is not done. You need to have a longer follow-up. And that is what Klosterhalfen and me, we're -- we know this situation for a long and that is the reason that we ask for building up these registries, and meanwhile, we're convinced that is -- that this is the responsibility of manufacturers for the post-market

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surveillance to build up these registries. Otherwise, you cannot get a good conclusion what are the risks for the device.

Q. Does a meta-analysis of studies such as you described in the NICE report give you more information to allow you to evaluate the risk of complications from the use of mesh in the treatment of stress urinary incontinence?

A. I hope you soon can be able to read our manuscript where we mention this. No, the meta-analysis is collecting several randomized controlled trials. You have an increased variation with this so the statistically analysis is even more nonsense, is meaningless in this, but because they analyze more clinical studies, they are able to detect more possible complications, therefore, they are helpful. You get a good overview what can happen, but they are not able to prove the safety because the power does not increase if you combine ten poor studies. That is, of course.

Q. Are you familiar with the

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Cochran review?

A. Yes. It is quite similar.

Q. Okay. Have you looked at the Cochran review of the use of mesh for the treatment of stress urinary analysis?

A. Yes, I remember there are two or three Cochran reviews in the past ten years, but they work in a similar way.

Q. So of what benefit to you are the Cochran reviews in understanding of the risks of complications from the use of mesh in the treatment of stress urinary incontinence?

A. They give a helpful analysis of what is represented by studies or what is published. They very often use similar studies so you find always the same studies in the various meta-analysis. But, again, even the Cochran review cannot prove the safety because all these single studies, they usually are underpowered.

Q. Doctor, we don't have a registry, you agree with me on that? We don't have a registry to look to as you would

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like to have to determine the complications that arise from the use of mesh in the treatment of stress urinary incontinence.

You agree with that?

A. Not completely. I know we have some in the incisional -- in the -- in the groin area, Ethicon has built up its own registry. We have in the field of hernias, we have some registries. There were some registries in Finland I've read in the internet for meshes in the pelvic floor without having access to the long-term data, only for the short term. There are some data pools in either Austria or Switzerland.

So I agree we don't have the data and the registries in the moment to make a decision which is the safe procedure or not. We have not access to this data, but there are a lot of data, but it is -- we don't have access to all of these data.

Q. What's the best data we have available to us to understand the risks of complications from the use of mesh in the treatment of stress urinary incontinence?

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What's the best we have?

A. To define the possible risks?

Q. Yes.

A. To define the possible risks, I agree the meta-analysis, the NICE analysis, the European analysis, the American analysis, they all raised -- the FDA analysis, it's a very excellent document, they all raised some concern and, therefore, all of these are reliable sources, yeah.

Q. So what is the best information we have available to us today to determine the rate of complications from the use of mesh to treat stress urinary incontinence?

A. The best -- there is no satisfying.

Q. There's nothing?

MR. ANDERSON: Objection. Form.

THE WITNESS: There is nothing satisfying. All of these data are incomplete. They are very, very limited. So the question which one of these limited studies is not as

limited as the other, yeah, you can think about it, but it doesn't help.

QUESTIONS BY MR. THOMAS:

Q. Okay. So if you were asked today to find out the rate of complications associated with the risk of the use of mesh for the treatment of stress urinary incontinence, you don't have anyplace to go, is that what you're telling me?

MR. ANDERSON: Objection to form.

Answer the question.

THE WITNESS: The only situation I would think that is relevant if you have a specific patient and she's asking you what do you think is the risk there.

QUESTIONS BY MR. THOMAS:

Q. So --

A. So then it depends whether it's young, whether there's comorbidities and so on. And then you can say within the first weeks it is a very low risk. That is probably an estimate that you can give.

Q. So if a doctor is treating a woman who has stress urinary incontinence and they're discussing about whether to use mesh to treat the stress urinary incontinence, where does the doctor go to understand the nature of the risks associated with that mesh?

A. He has to go to his own experience. So whether -- if he made a follow-up investigation of this patient and that is something that has to be required more and more, you need some backup from the surgical communities, you have to re -- or you have to underline the importance of follow-up investigations so that you have your own experience. You have to go to the literature, you have to go -- you take the information of the companies and that is what you can provide to the patient. And you have to think about the long-term -- possible long-term complications and that, yeah -- and you have to address some specific risks of the patient, that is the discussion about the possible disadvantages and advantages in a

specific situation.

MR. THOMAS: Let's stop for the day.

MR. ANDERSON: Okay.

MR. THOMAS: Thank you, Doctor.

(Off the record at 5:57 p.m.)

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CERTIFICATE

I, CARRIE A. CAMPBELL, Registered Professional Reporter, Certified Realtime Reporter and Certified Court Reporter, do hereby certify that prior to the commencement of the examination, Uwe Klinge was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

_____

CARRIE A. CAMPBELL,
NCRA Registered Professional Reporter
Certified Realtime Reporter
Missouri Certified Court Reporter #859
Illinois Certified Shorthand Reporter #084-004229
Notary Public
Dated: November 26, 2013

ACKNOWLEDGMENT OF DEPONENT

I,______________________, do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____

Prof. Dr. Med. Uwe Klinge DATE

Subscribed and sworn to before me this ________ day of ________________, 20 ______.

My commission expires: ________________

Notary Public

ERRATA

PAGE	LINE	CHANGE/REASON

LAWYER'S NOTES

PAGE	LINE	

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC, REPAIR SYSTEM PRODUCTS, LIABILITY LITIGATION	) MASTER FILE) NO. 2:12-MD-02327)) MDL NO. 2327
THIS DOCUMENT RELATES TO CAROLYN LEWIS, ET AL. V. ETHICON, INC. CASE NO. 2:12-CV-04301	) JOSEPH R. GOODWIN) US DISTRICT JUDGE

FRIDAY, NOVEMBER 15, 2013

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Deposition of Prof. Dr. Med. Uwe Klinge, Volume II, held at the Quellenhoff Hotel, Monheimsallee 52, 52062 Aachen, Germany, commencing at 8:35 a.m., on the above date, before Carrie A. Campbell, Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter, and Certified Court Reporter.

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(Klinge Exhibit 12 marked for identification.)

MR. THOMAS: Before the deposition, I told Mr. Anderson during the inquiry yesterday about the redacted exhibit concerning the meeting in Suvretta in 2003. I've been advised that the company has already produced an unredacted copy of that document in another production. I've asked for it and hope to have it when they wake up. So I'll produce it to you as soon as I have it.

MR. ANDERSON: Thank you for doing that.

DIRECT EXAMINATION (Witness previously sworn)

QUESTIONS BY MR. THOMAS:

Q. Doctor, when we closed yesterday, we were talking about who a doctor could consult with to understand the risks related to the using of mesh for the treatment of stress urinary incontinence.

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Do you recall that?
A. Yes.
Q. And I believe you identified for me an organization in Germany that you called the AWMF; is that correct?
A. Yes.
Q. Let me show you what I've marked as Exhibit Number 12. As I understand it from those people who looked for me, Exhibit Number 12 is an English version and the short version of the AWMF registry for the diagnosis and treatment of stress urinary incontinence in women.
Is that fair?
MR. ANDERSON: Objection.
QUESTIONS BY MR. THOMAS:
Q. Are you familiar with this document, Doctor?
A. With this English, no, I never read it.
(Klinge Exhibit 13 marked for identification.)
QUESTIONS BY MR. THOMAS:
Q. Let me hand you what's been

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marked as Exhibit Number 13. It's the long version, and it's in German.
Do you recognize that document?
MR. ANDERSON: Well, objection. This is a 62-page document and if you want to ask him if he has -- if by the cover of this or he can read 62 pages.
MR. THOMAS: All I want to know, Ben, is whether this is the organization that he discussed yesterday consulting online for the guidelines for the treatment of stress urinary incontinence. I don't want him to read the whole document. We don't have time to do that.
MR. ANDERSON: Different question.
Is this AWMF the organization that you mentioned yesterday as far as you can tell?
THE WITNESS: Yes. I mentioned this.
QUESTIONS BY MR. THOMAS:
Q. And did you consult the

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guidelines that you discussed yesterday online on the computer?
A. Please, I had to look, sorry.
Q. I am sorry.
When you referred to the AWMF guidelines --
A. Yeah.
Q. -- did you go to the computer to consult the computer to find those guidelines?
A. When I hadn't looked to this, yes.
Q. Do you have a hard copy of the guidelines from the computer?
A. No.
Q. All right. Do you know whether Exhibit 13 are the guidelines that you looked at online?
A. I tried to figure out the date of when these guidelines have been finished because I know that there are at least two different versions; an older version and a more actual version there. And, therefore, yesterday I mentioned this phrase that has

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been changed in the documents I saw when I made my research. It's somewhere in the text. If you like, I can try to find it here, but it's the recommendation of surgical therapy.
Q. Okay. I don't want to do that.
A. So I'm not sure whether this is the last version here.
Q. That's fine.
(Klinge Exhibit 14 marked for identification.)
QUESTIONS BY MR. THOMAS:
Q. Let me hand you what's been marked now as Deposition Exhibit Number 14. Deposition Exhibit Number 14, Dr. Klinge, is a document titled "EAU Guidelines on the Surgical Treatment of Stress Urinary Incontinence."
Simple question, have you seen this document before?
A. No, I've not seen it.
Q. And the date on it is September the 7th, 2012, when it was accepted and published online on September the 17th, 2012;

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is that correct? On the left right in the middle?
A. Yeah. That's correct.
Q. Are you familiar with the European Association of Urology?
A. No.
(Klinge Exhibit 15 marked for identification.)
QUESTIONS BY MR. THOMAS:
Q. Let me show you what's been marked as Deposition Exhibit Number 15.
Exhibit Number 15 is a document titled Guidelines on Urinary Incontinence, Text Update, March 2013. It reads, "This pocket version aims to synthesize the important clinical messages described in the full text and is presented as a series of evidence summaries and graded action-based recommendations which follow the standard for levels of evidence used by the EAU."
Have you seen Exhibit Number 15 before today?
A. No, I haven't seen it.
Q. Doctor, are you familiar with

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an organization known as the American Urological Association?
A. Familiar, if you mean that I have ever heard of it or noticed it, I think so, yes.
Q. Do you consider the American Urological Association to be authoritative in the field of stress urinary incontinence treatment?
MR. ANDERSON: Objection. Dr. Klinge is not a urologist and he's not here being offered as a urologist nor the treatment options of SUI, and as I stated yesterday, and so all of these questions about treatment recommendations for a urologist or a urogynecologist clearly are outside of the scope of his expert report and the reasons that he's being offered as an expert. If counsel wants to continue to ask questions about it, but I'm going to move to strike all of it.
QUESTIONS BY MR. THOMAS:
Q. Do you consider the American

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Urological Association to be authoritative in the field of treatment of stress urinary incontinence?
A. I cannot comment on this. I know from my colleagues here that there are various societies taking care of the problem of incontinence and they're competing. They're sometimes with -- conflicting with different assumptions, different advices or less.
To my knowledge from all of the discussions with them, there is not one single society that is authoritative, yeah, that is able to give recommendations for the woman either treated by urologist or gynecologist. But, of course, you find a lot of these different societies. Maybe this is an expression that there are different opinions as well.
Q. And you said, "I know from my colleagues here." Is that conversations that you've had with colleagues at the hospital where you work?
A. Yes. We have a close

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collaboration with Professor Kirschner-Hermanns, for example, she has been the leader of the incontinence center.
Q. And that's the incontinence center at the hospital that's part of the university?
A. Yeah.
(Klinge Exhibit 16 marked for identification.)
QUESTIONS BY MR. THOMAS:
Q. Let me show you what's been marked as Deposition Exhibit Number 16. This is titled "Position Statements of the American Urological Association." It's dated at the bottom November 2011.
Is it fair to understand that you've not seen this position statement of the American Urological Association?
MR. ANDERSON: Same objections I stated before.
THE WITNESS: I don't recall whether this is exactly. I recall that I have seen some recent position statements by some of these societies,

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but it's not my focus to list all of these various societies and various aspects.

(Klinge Exhibit 17 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Let me show you what I've marked now Deposition Exhibit Number 17.

Deposition Exhibit Number 17 is from the American Urogynecologic Society, and it's titled "Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders."

Have you seen Exhibit 17 before?

A. Maybe. I'm not sure.

Q. Did you consider the position of the American Urogynecologic Society in the formation of your opinions in this case?

MR. ANDERSON: Objection. Same objection before.

THE WITNESS: Please, can you say it again?

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QUESTIONS BY MR. THOMAS:

Q. Did you consider the position of the American Urogynecologic Society in the formation of your opinions in this case?

MR. ANDERSON: Objection. The question is not fair.

Do you want him to read the entire document because how could he know whether he considered the position if he doesn't know what it is. My objection stands. He's not going to be asked any of these questions and you know that and it's not anywhere in his report nor is it in his reliance materials, but if you want to keep asking, please, feel free to.

MR. THOMAS: Thank you, I will. I have a limited amount of time here.

MR. ANDERSON: You do.

MR. THOMAS: You can have a standing objection to that.

(Klinge Exhibit 18 marked for identification.)

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QUESTIONS BY MR. THOMAS:

Q. Doctor, are you familiar with the International Incontinence Society?

A. Yes. I know them.

Q. Let me hand you what's been marked as Deposition Exhibit Number 18. Deposition Exhibit Number 18 is titled "ICS Fact Sheets, A Background to Urinary and Fecal Incontinence," prepared by the publications and communications committee, July 2013.

Have you seen this document before?

A. Not as a printout version, but I repeatedly am going to the website because they offered a lot of interesting tools for making research and how to investigate all these. So it's an interesting website from the society.

Q. Do you --

A. And among this, there is -- I made a lot of downloads from the society.

Q. Why did you do that?

A. Because I'm interested. I want

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to be informed of what happens. There's so many contradicting information and to get an overview, yeah, I'm a scientist and, therefore, it is my duty to go into the problems.

Q. Let's go --

A. To try to learn of it.

Q. Let's go to page 13 of Exhibit 18, please.

On the left side, the second full half reads, "Definitive therapy for SUI is surgical and involves restoring urethral support through use of a sling. Worldwide mid-urethral slings comprised of synthetic mesh have become the treatment of choice for SUI. Long-term data are robust and demonstrate durable efficacy and a very low complication rate particularly in experienced hands."

Do you agree with that statement of the ICS?

MR. ANDERSON: Same objections.

THE WITNESS: The -- I don't think that I'm -- in the moment that

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I'm able to give an opinion in what woman, at what stage of the disease, what therapy may be the best.

When they said here they are a low complication rate, we talked about what does it mean low, can we be sure that it is low, that is a question we can have intense discussions about it.

My topic or my -- so far as I understood, my question was whether the use of the Prolene®, when it is coming to complications, whether this is a problem of the material. Whether there are some basic requirements that makes it imperative to use the most heaviest weight mesh from a hernia surgery for the use of this. That was the question that I wanted to address by looking all these things.

So even if there is only one patient with a complication that is not necessary because of using the wrong requirements, that was the question that I wanted to address.

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But I'm not able to say their requirements for the societies or so. And I have no doubt that there are some patients taking a big benefit by the use of slings.

(Klinge Exhibit 19 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Let me hand you what I've marked now as Deposition Exhibit Number 19. Deposition Exhibit Number 19 --

A. Yeah, that is the NICE, yeah, the National Institute.

Q. Is NICE -- it's called -- it's titled "Urinary Incontinence, the Management of Urinary Incontinence in Women," issued September 2013. And it's issued by the organization called NICE, the National Institute For Health and Care Excellence.

Is this the document to which you referred yesterday in your testimony?

A. I downloaded, if I remember correctly, about 10, 15 documents from the website from NICE. So this is one of it.

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Q. Why did you go to the NICE website?

A. Same answer as some minutes before; to get informed the search and literature is one of our most important tools and -- there has been -- in February -- last year the question whether we have access to all of these things and I would like to point out that at the university we have an almost unlimited access to all things that are published there to correct this impression that it is restricted to the journals I get personally.

Q. I didn't suggest that.

A. No, it was from the last year or in February there has been the discussion, there has been the question whether do our -- getting these specific journal and I just wanted to take this opportunity to clarify that we have huge possibilities to access.

Q. I understand that.

The computer is a wonderful thing, isn't it?

A. It has changed completely our

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work.

Q. Doctor, let's go back to your report, please, which is Exhibit Number 11.

On page 2 of Exhibit 11 under the summary of your opinions, you say, "The mesh -- excuse me, the Prolene® mesh in TVT® is a heavy-weight mesh --

MR. ANDERSON: Can you show us where you are?

MR. THOMAS: Right at the top of the page.

MR. ANDERSON: Thank you.

QUESTIONS BY MR. THOMAS:

Q. Doctor, in page 2 of Exhibit 11, you state in your report under the heading, "The Prolene® mesh in TVT® is a heavy-weight mesh ('over engineered').

In that paragraph, you say, "Any pelvic mesh designed with this much excess surface area and weight unreasonably increases the risk of injury to the patient and is a less safe design."

Did I read that correctly?

A. Yes.

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Q. And my question is when you say that this mesh design unreasonably increases the risk of injury, compared to what?
A. To a material -- that is, in fact, the most important thing, you have to do it in comparison. If you compare the 108 grams of the Prolene® mesh with the 42 grams of Gynemesh® for the 34 grams of ULTRAPRO™, it has a surplus, it has more material, it has more surface. So if you compare these two, you have more contact area to the tissue and, therefore, you will have intensified tissue reaction.
So if there is no need to have this amount of material, if you can reduce it, if you can produce, if there are some facts that allow you to reduce the amount of material of the Prolene® mesh by half, then you will have an improved tissue reaction and, therefore, you will lessen the scar formation, you will lessen the risks for the patient. That is it. Prolene® mesh is at the maximum. In comparison to all other meshes, it's the maximum of the weight of the

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material that is placed in this area and, therefore, it is, of course, it is heavy-weight. I think it's the heaviest monofilament mesh that I know, and if you can reduce the amount of material, that has been the sense of our work, then you improve the tissue reaction and reduce the risk.
Q. Didn't we decide yesterday that weight was not the determining factor in the intensity of the foreign body reaction?
MR. ANDERSON: Objection to form.
Go ahead.
THE WITNESS: In fact, that is -- yeah. If you have a Prolene® with these fibers and just reduce the amount of material, using a similar fiber, the same fiber, but just reduce the amount of material, of course, you will increase the pore sizes, you will reduce the material and you will improve the tissue reaction.
If you just stick to the weight and change the fiber from 120 microns

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to 2 microns and create a multifilament made of polypropylene, then you are right, completely right. That is -- but this has been a -- an important part of our discussions because we, that is coming from Aachen, that is -- has been our work to stick on the importance of the pores and not of the weight.
So but sometimes it is more easy to reduce it to this to make it better understandable for the people.
Q. Doctor, do you have any clinical data to which you can point to support your opinion that the Prolene® mesh increases the risk of injury in the treatment of stress urinary incontinence above other materials for the same application?
MR. ANDERSON: Objection.
THE WITNESS: As I pointed out yesterday, the clinical data unfortunately that are provided, they are too limited to allow this consequence; however, the basic

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principle that heavy-weight, a huge amount of material locally, small pore size, that this is linked to an increased risk, there are several studies showing it and not least because of this in the guidelines, in the meta-analysis for surgical meshes for hernia repair they're usually already is a statement that you have to consider light-weight and large pore.
QUESTIONS BY MR. THOMAS:
Q. You referred to a meta-analysis for surgical meshes for hernia repair.
Have you considered the meta-analysis for the use of meshes for stress urinary incontinence?
A. We mentioned yesterday I'm deeply aware about the fact that the limited value of meta-analysis.
Q. Okay.
A. It just -- it is helpful to confirm the importance of weight and pore size. In general, that this is -- that has a

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strong impact of the clinical results. There is no doubt about it. But as I pointed out yesterday, it is impossible to see or to prove any inferiority or superiority of any specific device.

Q. Also in your answer, you referenced several studies showing this basic principle.

Are these all animal studies?

A. No, there is -- if you are -- if you're trying to figure out what is the relevance of this mesh material discussion in the field of hernia surgery, and the field of hernia surgery is a little bit older than this for the pelvic floor and a lot of -- and we introduced the meshes, I think, earlier, if you try to figure out what is the relevance there, then you find there are several meta-analysis meanwhile summarizing clinical studies, and there are guidelines for the clinical treatment based on these clinical trials and giving the recommendation to use large pore material, reduce light-weight meshes in the treatment -- for

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the treatment of hernia patients.

So that confirms that the principle to think or to consider the mesh material and the weight and the pore size, that is well-accepted in the hernia society, yes.

Q. Is it fair to understand, Doctor, that you're relying upon your training, education and experience in connection with the care and treatment of hernias to support your position that mesh used in the treatment of stress urinary incontinence has the same risks as the mesh that's used in hernia repair?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: Of course, my knowledge of the Prolene® is based on our preclinical studies that we did in the animal models, from our clinical experience, from the experience we have got from hernia patients. Overall, everything confirmed that the tissue response is quite similar.

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That there are some similarities when you place meshes in living tissue, that you have some similarities. There are -- depending on the specific location, there can be some differences in the tissue reaction, but there are very important aspects that are quite similar that a mesh behaves similarly in the various areas from the point of the histological analysis.

There are considerable differences in the biomechanics and there we know that pelvic floor has different biomechanics. We have a similar area in the reenforcement of the diagram where we have some forces as well. So the biomechanical problem makes it as a functional difference to the hernia mesh. That is even more in another respect when you're taking a hernia mesh to use it in another functional condition. It's a concern and problem.

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QUESTIONS BY MR. THOMAS:

Q. Let me try my question again and maybe you didn't understand it.

What I'm trying to understand, we were talking about clinical studies used to analyze the extent to which mesh causes problems in the pelvic floor -- strike that.

The goal of my question was to try to determine whether there are clinical studies on which you rely to analyze the problems of complications with the use of mesh for the treatment of stress urinary incontinence, and I think you told me that you rely on your clinical experience in hernia for that information.

Is that true?

MR. ANDERSON: Objection to the form of the whole question.

Go ahead.

THE WITNESS: No, that is, of course, not true because to my opinions, it is -- it is necessary to see whether there are some complications when using it as a

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sling, and as you know from the documents, there are some specific complications which are different from those from hernia surgery. So you have to look to the specific literature what may be some consequences.

However, the general opinion whether it's heavy-weight, whether it's a higher risk than another, you have to take all of this information together.

QUESTIONS BY MR. THOMAS:

Q. Okay. Is it your testimony that you need to go to the specific literature to learn what may be the consequences of the use of mesh for the treatment of stress urinary incontinence?

A. You have to consider this as well. You have to include it into this.

Q. What literature have you considered to understand the complications which arise from the use of mesh in the treatment of stress urinary incontinence?

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A. I'm not able to give you a list of all of the documents I've downloaded during the past years. I regularly are looking to the literature, and I know it's hundreds of documents every week are coming, some new. So, yeah, several. I looked at several of them.

Q. Can you tell me one?

A. One of these publications?

Q. Yes, just one.

A. Sling. As I told you, it's the NICE meta-analysis.

Q. Okay.

A. That their -- it is -- as I told you, the AWMF, it is study for PVDF meshes from Norway that has been published this year. There has been several studies comparing the textile properties.

Q. Are there any clinical studies about which you're aware that suggest that the design of the Prolene® mesh increases the risk of injury to a patient over a larger pore, lighter-weight mesh?

MR. ANDERSON: Objection again.

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Asked and answered.

Go ahead.

THE WITNESS: I did not know that there has been a comparison of different materials as it has been done in the hernia -- in the field of hernia surgery where we make randomized controlled trials comparing light-weight and large pore meshes. I don't know whether -- I don't know in the moment a study where someone compared two different slings with the outcome. But as we discussed yesterday, clinical studies are very limited in clarifying whether one material really is better than the other. It is very likely that if you make such a study that you get nonsignificant results due to the variation in your collectives.

QUESTIONS BY MR. THOMAS:

Q. Is it true, simple question, that there are no -- it's true that there are no clinical studies about which you're aware

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that suggest that the design of the Prolene® mesh increases the risk of injury to a patient over -- in the treatment of stress urinary incontinence over a larger pore, lighter-weight mesh; is that true?

MR. ANDERSON: Objection. Asked and answered again.

THE WITNESS: It isn't true because you didn't reduce it to the pelvic floor. So if you made it in general --

QUESTIONS BY MR. THOMAS:

Q. Oh, I think I did.

A. You just asked me if I'm correct. If there are clinical studies showing that Prolene® has more complications in comparison to heavy-weight or I missed it. So a general, there are clinical studies. For the use as sling, I don't know any.

Q. Okay. So just to make sure we're clear. For the use of slings, mesh slings, in the treatment of stress urinary incontinence, you're unaware of any clinical studies that show that the use of Prolene®

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mesh increases the risk of injury to a patient in the treatment of stress urinary incontinence over a larger pore, lighter-weight mesh; is that true?

MR. ANDERSON: Objection. Asked and answered.

THE WITNESS: That is true.

QUESTIONS BY MR. THOMAS:

Q. Okay. Doctor, on page 2 of your report, you continue and say, "The Prolene® mesh in TVT® is a small pore mesh."

How big is the pore in TVT® used for the treatment of stress urinary incontinence?

A. This is -- this is a question that is -- that has to be explained in detail from various aspects. It is insufficient to just make a measure in one dimension and say this is a pore.

In the '90s, we made with the VYPRO mesh with 3, 4, 5 millimeters of pores roughly when you make these measurements. So these are considered really as large pores. There are others that are from the

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microscopical view can be regarded as small pores. So to make a precise measurement of the pore size or the distribution of the pores, it was a problem for a long time.

We first started in 2000, I think, for the first time that we tried to figure out that it is a distribution, that every mesh has some smaller pores, some larger pores. So one specific value -- yeah, figure and value of a pore, this does not reflect the reality of a mesh construction. So you have these different pore sizes in every mesh.

And then we got aware that if you look to the histology and not to the foreign body reaction around the filaments but to the pores inside, then you see the differences that in the VYPRO and the ULTRAPRO™, you don't have this bridging and there are, if the filaments are coming closer together, then you have these pores filled by scar tissue. So there seems to be a difference.

In 2003, 2004, we started to

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get objective analysis of this pore distribution. To make it easier to understand what was found in histology, to make it easier to understand what are the consequences if you change something of the textile construction, what is the consequence to the pore sizes and the distribution of the pores, therefore, we made this machine or we developed this machine together with Professor Mühl and it was able to get clear images of a mesh construction and if you are using the textile porosity as before, you get this distribution.

The next decision has to be how to compare distributions to define which is better than the other. And it is statistically, scientifically it is not easy to make a reliable comparison of distributions and, therefore, we decided to make a cutoff, to define a cutoff because we have seen at various histological sections that there may be a minimum pore size that is increasing the risk for this bridging. It has been with the Marlex. It has been done

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for the first time with the Marlex, and we have -- somewhere in your documents there is a PowerPoint slide with a distribution and then there is on the left side, there is a distribution for the Marlex and there we marked in between 600 and 800 microns that we saw and we measured the distance of the filaments that we saw that below this border of 600, 800 with the Marlex and you have this bridging.

Later on, 2003, 2002, we took as a limit -- as a cutoff to separate the meshes with low risk and high risk by 1 millimeter because we then had the values of the experiments that has been published by Conze where we measured it in Aachen.

But at the beginning, we noticed that there is an impact of the polymer so we separated for PVDF and PP. Of course, there are a lot of other impact factors that can do it.

So the question what is small or what is the best pore or what is the pore cannot be answered by giving you just a

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figure. If you take the extremes, the ULTRAPRO™, the VYPRO, was a pore of 3 to 5-millimeter. If you made a linear measurement there with all of the limitations, all restrictions, please don't stick me to this number 3 to 5-millimeter. It's just a shortening of this. This is low risk for bridging, and whereas, very small pores has a high risk of bridging. That is the message.

Q. Doctor, have you ever attempted to physically measure the pore in the Prolene® mesh used in TVT® for stress urinary incontinence repair?

A. Whether we made a measurement of the Prolene® mesh?

Q. Yes.

A. Dr. Mühl did it.

(Klinge Exhibit 20 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. And I'm not -- and just for the record, what you're talking about is Exhibit Number 20, the article that you coauthored

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with Dr. Mühl in 2007, "The New Objective Measurements to Characterize the Porosity of Textile Implants."

Is that correct?

A. Yes.

Q. My question is in the 1990s when you're doing your experiments, did you ever measure the pore size of the TVT® mesh used -- strike that.

In the 1990s when you were studying first generation Prolene® mesh, which you call old Prolene®, did you ever measure the pore sizes?

A. The pore sizes in the '90s have been done first by just making linear measurements. We know -- we all know that this is not accurate to give a good reflection of the pore size, but at that time, it was the way we did it, and the next thing we tried to do is the textile porosity. So it is impossible. It is still today impossible to measure a pore size.

Q. Okay. Still today impossible to measure a pore size, correct?

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A. It depends from your definition what you're thinking of as a pore size. What is -- of course, you can make images of the pore area so -- first of all, you have to define what is your meaning of pore size, in what context you want to have this. General finding.

Q. Doctor, are you -- I am sorry, I didn't mean to interrupt you.

A. Yeah.

Q. Doctor, are you aware of any standard that tells you or Ethicon how to measure pore size?

A. I think -- or the -- the best solution to get an idea or to try -- an objective measurement to make a characterization of textile structures by the use of pores, this is done in this publication.

Q. Okay. Other than the Mühl publication, Exhibit Number 20 that we've talked about before, are you aware of any standard promulgated by any regulatory, public health authority or company that tells

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you or Ethicon how to measure its pore size?

A. I know there are some -- there has been some publications related to the textile porosity. How to make the textile porosity in a two-dimensional way. There are some -- there are maybe some experimental other attempts to grasp the problem of pores to describe this. But there is, of course, I don't know any official standard showing you have to do it like this.

Q. In the '90s when you were doing your own studies, you measured them in a linear fashion; is that true?

A. At the beginning, yes.

Q. Okay. And tell me how you did that. What points in the pore did you measure?

A. As I remember, we had a visual impression what may be the mean distance in the pore. Not looking what is the farest distance, what is the shortest, but what may be the mean roughly.

But, again, the purpose at that time was to give a hint to the reader, to

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show the difference between 3 millimeters and .3 millimeters. And, therefore, this gives a good impression that the textile construction was different.

Q. Before VYPRO, was there anything in the literature about light-weight -- strike that.

Before VYPRO, was there anything about a comparison of large pore to small pore in the literature?

A. I'm not aware of it, no.

Q. Before VYPRO, was Prolene® known as a large pore mesh?

A. These words were not -- it was not a discussion. At the beginning of the '90s, you already had the Mersilene. Mersilene is a mesh with a very low weight. You had the Prolene® with very high weight, and there hasn't been any discussion about the different textile characteristics. I think that is what we introduced. If you look to the literature what has been published until '99 with the search for meshes, you will hardly find any good data up

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to there. It's a dozen experimental studies until this and then it's going up.

Q. Was the first generation 6-mil Prolene® mesh used for hernia repair, which you refer to as old Prolene®, ever described in the literature as large pore macroporous mesh?

A. In what -- before 1995, that has not been the wording for -- to describe a experimental setting there. Yeah, later on, I know that there is some of the documents where we took over -- I think ourselves took over some measurements provided by the manufacturer and said -- or took it in and mentioned it as 1.2 millimeter, the pore size.

So, but, yeah, as we discussed already, it is not sufficient to give a real impression of pore. It's too difficult.

Q. Doctor, we spent a lot of time yesterday talking about the progress in your understanding about the design of meshes beginning in the party in Christmas in 1993?

A. Uh-huh.

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Q. At any time in your research from 1993 to the present, in your experience, was it ever appropriate to describe Prolene® as a large pore macroporous mesh?

A. It is in contrast. If you're looking to our experimental publications, there we took the Prolene® mesh in our experiments as a control for a mesh that is usually bridging, that induces usually an intense inflammatory and fibrotic reaction. That was our control for many of these experiments.

And on the other end, we really had some large pores, light-weight mesh materials, but the prototype of a heavy-weight, small pore meshes, that has been Marlex and Prolene®.

Q. My question, Doctor, is a very simple one and I'm trying to understand whether based on your 20 years of experience in this field, at any time during that 20 years whether the state of knowledge about mesh design was such that it was appropriate to describe first generation 6-mil Prolene®

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mesh as large pore and macroporous?

MR. ANDERSON: Objection to form.

THE WITNESS: No. No. It is --

QUESTIONS BY MR. THOMAS:

Q. You're familiar with the Amid classification?

A. Uh-huh.

Q. Is that "yes"?

A. Yes. Yes. Sorry.

Q. And you know under the Amid classification that Prolene® is a Class I mesh? Is that "yes"?

A. Yes, I know it, but I have to explain this is not fair because now we are switching to different definitions of large pore.

Q. Okay.

A. I --

Q. Can I --

A. From our work, it is very clear what large pore is. That is a large pore. The consequence of a large pore that you have

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a low risk for bridging. That is the message of all our work, and this shouldn't be put together with the definition of large pore in the Amid classification because he has a different aim and purpose to do so.

So it is mixing up two different things and it is increasing the confusion that everywhere happens.

Q. You've talked about the Amid classification at length in other depositions and I'm not going to explore that again, but feel free --

A. Me neither.

(Klinge Exhibit 21 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, I've handed you what's been marked as Exhibit 21.

Exhibit 21 is a --

MR. ANDERSON: Excuse me, Counsel, can you tell me what the F mesh is? Mine is cut off.

MR. THOMAS: Yeah, mine is too. I was just going to say that for the

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record, but I can't, but I'll get them for you.

QUESTIONS BY MR. THOMAS:

Q. Exhibit 21 a journal article in the International Urogynecology Journal, volume 19, number 5, May 2008, it's titled "Tensile Properties of Five Commonly Used Midurethral Slings Relative to the TVT®."

You cited this article in your paper, haven't you? Do you remember that?

A. Cited in what --

Q. In your report?

A. Yes. Yes. It's very nice, very interesting study.

Q. And this study compares the tensile properties of five different slings against the Johnson & Johnson TVT® sling, correct?

A. The textile properties, yeah.

Q. Okay. I want you to turn to page 657 of Exhibit 21, to Table 1.

And Table 1 shows, "The textile properties (including loaded failure) provided by the manufacturers listed at the

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top (AMS, American Medical Systems) describing the different meshes tested in this study.

Have you looked at this table before?

A. Yes.

Q. And there are six different types of meshes that are used for the treatment of stress urinary incontinence; is that correct?

A. That is correct.

Q. And the authors in the Moalli paper have a category for mesh thickness, correct?

A. Yes.

Q. And mesh thickness is exactly what it says, it's just how thick the mesh is?

A. Yes.

Q. Then it has pore size and it shows the pore sizes for each of these meshes used for the treatment of TVT®, and you understand that Gynecare is the TVT® mesh, correct?

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A. Yes.

Q. And the Gynecare mesh is shown as having a pore size of 1,379 microns, correct?

A. It is written here, but we pointed out, I think, very extensively that the number of 1,379 microns is a measurement within the textile mesh, but it does not reflect the textile characteristic in regard to pores and porosity because you always have a distribution.

But you see still here in the year 2008, it was still used there, but this is not what is the relevant information to predict the tissue reaction there.

Q. Do you view --

A. So it's not relevant. It's not really relevant.

Q. Okay. Is it inappropriate from a scientific perspective for the authors in the Moalli study, Exhibit 21, to regard pore size in this fashion?

A. No, it is -- no. It is -- a lot of people is doing it when they don't --

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when they were not aware of the problems of this. You cannot discuss every parameter in detail in every manuscript, otherwise, you -- so every manuscript is a comprise. You can present some data.

But in this litigation, we're sitting here and discussing about the pores of the Prolene® and when you cited this document as proof that Prolene® is a mesh with pore size of more than 1,000 microns, that is -- that is not relevant. It is a -- it is a paper, it is a manuscript and they did the best to take the information they got there, but it doesn't help me for my opinion whether it's a small pore or large pore. That is the fact that has to be clear, I think.

Q. I understand that. I actually am going to use this for a whole different reason than you think.

A. I'm not sure.

Q. I know that, but that's why I get to ask the questions.

A. And I have to be concerned.

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Q. No, you don't.

So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?

MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?

THE WITNESS: No.

QUESTIONS BY MR. THOMAS:

Q. Have you looked at the mesh manufactured by AMS for the treatment of stress urinary incontinence?

A. No.

Q. Have you looked at the mesh manufactured by BARD for the treatment of stress urinary incontinence?

A. No.

Q. Have you looked at the mesh manufactured by Caldera for the treatment of stress urinary incontinence?

A. No.

Q. Have you looked at the mesh manufactured by Mentor for the treatment of stress urinary incontinence?

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A. No.

Q. Are you aware of any other mesh marketed in the United States for the treatment of stress urinary incontinence other than the ones listed in Exhibit 21?

A. Aware in the meaning that I know that there are several others. I'm not -- I'm not able to present the total list of all possible sling materials there.

Q. Okay. The PVDF mesh for the treatment of stress urinary incontinence is not available in the United States.

You agree with that?

A. To my knowledge, it is correct.

Q. And the PVDF mesh from FEG that's used for the treatment of stress urinary incontinence has not been approved by the United States Food and Drug Administration.

Do you agree with that?

A. It is -- yeah, to my knowledge, it is the fact. But I'm not sure whether they really sent it to them to have it checked.

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Q. I understand.

A. Or whether they didn't do it.

Q. I don't know whether they've asked either, but --

A. But this is -- I think this is a major difference.

Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used for the treatment of stress urinary incontinence, the Ethicon TVT®, has a pore size that's larger than the other five that are listed in the Moalli study?

A. No.

Q. Why?

A. Because the question what is the pore size, whether it's bigger than the other, it cannot be answered. You have this distribution. You have some pores bigger than the others. You have to make the testing or you have to figure out what is the specific distribution of the various pore size and then when you want to make a cutoff, when you include a cutoff, then you have to look to the effective porosity and then you

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can get an opinion whether one is better than the other.
Q. Okay. Have you ever analyzed the extent to which meshes available in the United States have an area of pore size that are larger than the Ethicon TVT® mesh, any of them?
A. Though even the information about the area has some limitations, but I have to say, no, I never made systemic analysis of the competitor -- of the slings from the competitors to have a systemic analysis of the other devices.
Q. It's your opinion that the Ethicon TVT® mesh used for the treatment of stress urinary incontinence does not have sufficient effective porosity as measured by, I think it's Exhibit Number 20, the Mühl study, to be used safely in a woman for the treatment of stress urinary incontinence; is that true?
A. The idea was or the facts are that when you look to the histology, reaction to this mesh material, you always hardly ever

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or always -- almost always find some bridging when looking to tissue around the Prolene® mesh. Therefore, it behaves biologically as a small pore meshes. Then if you -- and this is consistent to the measurements and this is consistent to the missing effective porosity in the Mühl testing.
So this is very, very consistent. If you look to the competitors, it is hardly difficult to find -- just to see the differences from the images between the various devices. So I think -- I assume that we will get similar results.
MR. ANDERSON: And you were pointing to page 658 of Exhibit 21 when you said "images"?
THE WITNESS: Yes. Figure 2 and --
QUESTIONS BY MR. THOMAS:
Q. Let me break down your answer a little bit.
When you measure pore size, it's your expert opinion that it's appropriate to use the effective porosity

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analysis that you and Dr. Mühl devised in Exhibit Number 20, correct?
A. Please can you rephrase the -- I didn't -- I'm not sure whether I got the first relationship in your sentence.
Q. When you measure pore size, it's your expert opinion that it's appropriate to use the effective porosity analysis that you and Dr. Mühl devised in Exhibit Number 20, correct?
A. I can say that the effective porosity that we mirrored from the study from Professor Mühl, they give some relevant, important information about the pores, the distribution of the pores in the Prolene® mesh. So, therefore, this is consistent with the histological findings and, therefore, my opinion is based or includes this one.
But it wouldn't be correct to reduce every statement about pores to the effective porosity.
Q. But isn't it true for purposes of your analysis of the extent to which a mesh is designed inappropriately insofar as

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there's adequate pore size for appropriate tissue integration that you rely on the study that you and Professor Mühl prepared, Exhibit Number 20, to determine the appropriate porosity measurement?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: It's a very long sentence, but I try to answer it however.
You have to understand that the measurement of Professor Mühl helps us to understand and to predict the tissue response.
If you assume the textile engineers from Ethicon would change the machine a little bit and the Prolene® really is a challenge for this machine. If they changed the machine a little bit and made the pores a little bit wider, then probably you get with the testing of the machine an effective porosity of maybe 40 percent, yeah.

In this case that the machine would have been changed a little bit, then we would have problems because in the histological analysis we saw the scar formation, we saw this bridging and, therefore, it is one way -- it is one important information, the effective porosity, and it helps to explain why certain devices have some problem.

And we would have serious problems if there is a mesh device, and I don't know whether the competitors have it, which may be 1.1 millimeter. So that you have an effective porosity, then the consequence for us would have to be to rise this limit. But in the moment, we feel consistent and satisfied with this limit.

QUESTIONS BY MR. THOMAS:

Q. Under the Mühl study that you and Professor Mühl did in 2007, Exhibit Number 20, is it fair to understand that

meshes with an effective porosity with less than 1,000 microns as measured by Professor Mühl, you believe present an increased risk of injury to patients?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: Yes.

QUESTIONS BY MR. THOMAS:

Q. And that meshes with an effective porosity of greater than a thousand microns -- strike that. Let me start over again.

Do you know whether any of the meshes on page 657 of Exhibit 21 have an effective porosity of greater than 1,000 microns as described in Exhibit 20?

A. No, I don't know.

Q. As you look at the relative pore sizes as measured by Moalli and others where you see that the Gynecare mesh has a pore size measured at 1379, all of the other manufacturers mesh sizes as measured by Moalli are lower, correct?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: Is it possible not to make a comment to this?

MR. ANDERSON: No, you have to answer the question, but you can --

THE WITNESS: I think it is inaccurate to compare textiles, different textile constructions by the use of these values for the pore size. It is inaccurate and insufficient.

QUESTIONS BY MR. THOMAS:

Q. Let me ask you this question, Doctor.

Do you know whether any mesh used for the treatment of stress urinary incontinence available in the United States has an effective porosity of greater than a thousand microns as measured by the Mühl study, Exhibit 20?

A. No, I don't know.

MR. THOMAS: Let's take a break, please.

MR. ANDERSON: Okay.

(Off the record at 9:46 a.m.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, did you have any involvement in the development of the 5-mil hernia mesh used by -- marketed by Ethicon for pelvic -- strike that.

Doctor, did you have any involvement in the development of the 5-mil hernia mesh marketed by Ethicon?

A. No, I don't have.

Q. Do you know whether the 5-mil hernia mesh marketed by Ethicon is still used today for the care and treatment of hernias?

A. No, I don't.

Q. Do you know whether the 5-mil hernia mesh made by Ethicon is appropriate for use in the treatment of any hernias?

A. For any hernias in the way that there may be some hernias that should be -- can be treated with this, yes.

Q. And under what circumstances would it be appropriate to use a 5-mil Ethicon hernia mesh?

A. If this is a -- in its textile properties comparable to what we know as the

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Prolene® mesh. If there aren't any severe differences because I'm not familiar with this mesh and its textile characteristics. It should be considered as a heavy-weight, small pore, very stable mesh material and the indication for these mesh materials in general from my point it's more or less the replacement of defect and not the use for the treatment of a hernia.

Q. When you say it's for the "replacement of a defect," what do you mean?

A. There are some cases where you have a complex defect of all tissues. There are various layers of tissues. In a hernia, you mainly have a hole and you have some stable surrounded tissue there and, therefore, the principle for the treatment of a hernia is to cover the hole with a wide overlap.

If you don't have this strong tissue that can cover the mesh, then it is necessary to have a more stable mesh with a restricted stretchability, otherwise you have a bulging here. And I think still the best

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indication for using these meshes are when you made a resection of the thoracic wall here in this field and when you want to make a repair in this area.

If you remove the ribs, then you need some very strong material without any significant flexibility.

Q. So would it be appropriate for a hernia surgeon in certain indications to use 5-mil hernia mesh for the repair of a hernia defect?

MR. ANDERSON: Objection. Asked and answered.

Answer it again.

THE WITNESS: There will be some specific indications where you have -- where the surgeon can have some good arguments to use this material, yeah.

QUESTIONS BY MR. THOMAS:

Q. Is Marlex mesh still an acceptable option for a hernia surgeon to use in the treatment of hernia patients?

A. You have to define what is

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acceptable. Acceptable in a legal way, yes, so all of these mesh materials that are permitted to be used in surgery can be used without any legal consequences.

If you're thinking of the possible risks for your patients, then it has to be seen in relation to the patient and the specific conditions and the specific hernia type whether you use a Marlex mesh, yes or not. There is no principle answer to this question.

Q. Based on your training, education and experience in mesh research and your experience as a hernia surgeon, would you ever use Marlex mesh in any of your patients?

A. As I told you, it is -- the basic question wouldn't be whether to use specifically Marlex or -- yeah, but the question would be whether to take a heavy-weight, stable, small pore, whatever you want to -- whatever you prefer to name these type of meshes. Whether you want to take these more stable meshes or whether you

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can reduce the amount of material to come to a satisfying result for the patient. That is the decision you have to do, and I can imagine that there are some conditions where Marlex is an appropriate -- Marlex or Prolene® or something like this is an appropriate selection.

Q. You've described one circumstance where you thought it might be appropriate to use a 5-mil Prolene® mesh for a repair.

Are there others that you can think of?

A. Maybe replacement in the brain, but I -- I don't -- or I do not have any specific condition in the moment where I think that it is necessary to use a mesh like Prolene® or Marlex.

Q. Over this litigation, I've heard a number of different estimates of the hernia surgeries conducted around the world in a year.

What is your current best judgment about how many hernia surgeries are

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conducted around the world each year? Using mesh, I am sorry.
A. I never counted it, but I've read this publication from Sanders and Kingsnorth. They estimate the use of meshes with about 20 million per year. I know that there are in the US about 1 million hernia operations a year. In Germany, it's about 300,000 hernia operations in the year. I guess India and China will contribute significantly, however, I don't know the figures.
Q. Do you have any information that allows you to estimate of the 300,000 hernia surgeries in Germany using mesh, how many use Prolene® 5-mil mesh?
A. For the treatment of groin hernia, I don't know any. For the treatment of incisional hernia, there will be some few that are still using heavy-weight meshes.
Q. And of the 300,000 hernias in Germany, do you have a breakdown into groin and incisional hernias?
A. Incisional hernia it's about

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30,000 to 50,000. And there is a -- maybe about 50, 60,000 infant hernias that are treated without any mesh.
Q. Of the 30 to 50,000 incisional hernias, which is I think the only category where you said it would be appropriate to use Prolene® 5-mil hernia mesh, what percentage of those incisional hernias would be treated with 5-mil hernia mesh?
MR. ANDERSON: Objection to form. Misstates -- mischaracterizes testimony.
Go ahead.
THE WITNESS: I do not have the -- I do not know the market shares. I know that the predominantly used mesh in Germany is the ULTRAPRO™. It is a large pore, small pore meshes in the groin and for incisional hernia, and I cannot remember in the past years anyone reporting about his experience with a heavy-weight, small pores, either Marlex or Prolene®.

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QUESTIONS BY MR. THOMAS:
Q. Do you include any other mesh, specific mesh brand names that are currently used when you describe the Prolene® 5-mil and the Marlex as a heavy-weight, small pore mesh, any other meshes on the market?
A. There are other manufacturers as Covidien and Brown. In Germany, there are, yeah, other manufacturers as well. So there are lots of -- finally Coda comes up with a list of 200 different mesh materials.
MR. ANDERSON: I'm not sure he understood your question. He was asking about how many other manufacturers make heavy-weight, small pore meshes.
Did you understand that?
THE WITNESS: Well, there are other -- yeah, there are some others from Brown, others from Covidien, others from AraVista.
QUESTIONS BY MR. THOMAS:
Q. Within your category that you've described as heavy-weight, small pore

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mesh, including as you describe it Marlex, the Prolene® 5-mil, do you know what percentage of the incisional hernia repairs use the heavy-weight, small pore meshes?
A. I don't have exact data. So far I have heard that market share of ULTRAPRO™ was about 70 percent in Germany.
Q. Does that mean --
A. So that will be the most easiest way to figure out what is the relationship between Prolene® and ULTRAPRO™ in Germany.
Q. Is it just as simple to say that the remaining 30 percent is a heavy-weight, small pore mesh?
A. No, all of these other manufacturers have light-weight, there's tie mesh, light-weight, material reduced. There's something midway. Again, we're coming into this confusion about the weight material.
Q. Okay.
A. The conclusion that everything else is heavy-weight is not true.

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Q. Okay. That helps me.
But what I'm trying to figure out, and maybe you don't know the answer to this, do you have any information that leads you to be able to estimate the percentage of heavy-weight, small pore meshes used for the treatment of incisional hernias?
A. Apart from this estimate, no.
Q. Okay. This estimate, I don't think you gave me an estimate.
A. Estimate is 70 percent market share of the ULTRAPRO™.
Q. Okay.
A. So at least it should be 70 percent.
Q. Okay. Doctor, on page 43 of your report, which is Exhibit 11, you begin your discussion of fraying/particle loss/MCM/LCM/curling/roping.
Do you have that?
A. I have it, yes, I see it.
Q. In 2012 when your deposition was taken, I believe your testimony at that time was that you didn't have any information

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that fraying, particle loss from mesh insofar as it related to pelvic organ prolapse created any injury of clinical significance.
MR. ANDERSON: Is that a question?
MR. THOMAS: Yes.
MR. ANDERSON: It doesn't seem like one. I'll object to mischaracterizing testimony.
QUESTIONS BY MR. THOMAS:
Q. Let me start over again.
As you sit here today, Doctor, are you aware of any literature that supports the contention that any fraying of TVT® mesh leads to clinically significant results in patients who receive the mesh for the treatment of stress urinary incontinence?
A. There is good evidence that fraying, increase of surface induces an inferior tissue response, but I don't know any clinical study testing the relationship between particle loss and the clinical outcome, and I cannot imagine that it can be done in a clinical study.

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Q. Is the same thing true for each of these categories that you have in heading G on page 43 of Exhibit 11, do you have any clinical data to link what you understand to be these conditions being fraying, particle loss, machine-cut mesh, laser-cut mesh, curling and roping, to any clinically significant conditions?
A. No, unfortunately, I did not find any study dealing with these problems.
Q. Doctor, the next several pages in the description of the fraying, particle loss section beginning on 43 of Exhibit 11, have you ever read any study that discusses risks associated with particle loss in vivo from Ethicon mesh used for the treatment of stress urinary incontinence?
A. I don't know any study that is testing the impact of this particle loss in an in vivo system.
Q. You were a hernia surgeon for how long?
A. I have been surgeon starting in 1985, and I'm still surgeon. I have been

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operating hernias from 1985 to 2006.
Q. Okay.
A. I'm not a hernia surgeon because in Germany you don't have hernia surgeons.
Q. I see.
Have you had any surgery -- have you done any surgeries since December 2006?
A. No. Not in humans.
Q. Do you still have your license to practice surgery if you like?
A. Yes.
Q. When you used mesh for the treatment of hernias, did you on occasion have to cut the mesh?
A. Usually you have to trim it, yes.
Q. And how do you trim it?
A. Outside of the OR field with specific other gloves to reduce the risk for contamination there, then you get some sterile scissors and you're cutting out of the OR because when you're trimming a mesh,

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always you have some sort of particle loss, always. There are some structures that create more. It depends on the bindings, it depends on the coarse of the filaments. So we know that there is some particle loss when you trim this mesh and, therefore, we did it outside and then we took the trimmed mesh and took these mesh and placed it in the groin or in the abdominal wall. So we try to avoid to trim it when it's already placed in the tissues.

Q. And is it fair to understand that for the approximately 20 million hernia surgeries conducted a year using mesh that you would expect those hernia surgeries to involve the trimming of the mesh in some way?

A. Yes.

Q. Do you expect based on your training, education and experience to the extent there was a clinical problem associated with particles being shed by mesh in vivo during the surgery that it would be reported in the literature now?

A. No. No. I don't think that

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the -- that it has -- that there has -- would have to -- or that there should be a report about this and I don't think that the absence of such a report indicates that it's not a problem.

Q. In the 20 years of mesh research that you've conducted, have you ever studied the clinical effects of particle loss from mesh?

A. We only studied in these years the impact of surface to bacteria adherence, to tissue response, cellular response. So increased surface means enhancement of this reaction. We never made a specific investigation whether reduction of particle loss by 10 percent leads to a change of this. We never did it.

Q. Did you ever consider analyzing the extent that particles shed by hernia mesh create any risk of injury in patients?

A. As I told you, we are convinced or we know that increase of surface will mean increase of tissue response and that means finally increase of scar and increase of the

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risks. In hernia surgery if you place a mesh 20 to 30 centimeters in a flat area and you made this trimming of some corners there in relation to the abdominal, surgical trauma, in relation to the mesh area, it is a considerably small area where there may be some effect.

We never selected a mesh material by thinking or asking for the amount of particle loss or, yeah, selected the mesh material with the least amount of particle loss. In hernia surgery, it was not an issue and I don't know anyone who is doing so.

Q. Prior to this litigation, in the 20 years of experience that you had in mesh research, did you ever identify a potential risk of injury to a patient associated with particles that are lost from a mesh during hernia implantation?

A. Only in the sense increased surface generally increases the risks but not specifically that we had some patient with a specific complication that can be related to particle loss, no.

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MR. THOMAS: I am sorry, I have to take a quick break again.

MR. ANDERSON: Okay.

(Off the record at 10:21 a.m.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, as a part of your opinions in this case, have you analyzed the extent to which you think that the Ethicon mesh used for the treatment of stress urinary incontinence sheds particles in vivo?

A. Can you please repeat the first word?

Q. As a part of your opinions in this case --

A. Yeah.

Q. -- have you analyzed the extent to which the Ethicon mesh used for the treatment of stress urinary incontinence sheds particles in vivo?

A. Sorry, whether we analyze it or whether --

Q. Yes.

A. We did made a systemic analysis, but I saw in one of the specimen

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that I was sent, that I got of the explants there are at least one area where you can be sure that this is a particle that has been there since the implantation.

There are a lot of other particles there, but you cannot be sure whether it's by dissecting for the histological preparation, but at least there is one and I made an image where this one particle can be seen there.

Q. We'll talk about that a lot later.

My question is -- I think you've already answered.

You've not made any systemic analysis to measure the extent to which the Ethicon mesh used in the treatment of stress urinary incontinence sheds particles in vivo; is that fair?

A. No quantitative analysis.

Q. Have you ever -- strike that.

Did you compare the extent to which Ethicon mesh used for the treatment of stress urinary incontinence compares to

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hernia mesh to determine the extent to which one sheds particles in vivo compared to the other?

A. Compared to hernia mesh?

Q. Yes.

A. I didn't get it.

Q. Have you made any kind of analysis to understand whether more particles are shed when you trim hernia mesh and implant it for hernia repair as compared to the placement of Ethicon mesh for the treatment of stress urinary incontinence?

A. First of all, it is similar mesh. It is mainly similar textile structures so when you cut these mesh structures, I wouldn't expect that there is any difference. The extent of trimming during the gynecological or urological operation, I don't know.

Q. Okay. Would you expect any particle loss between the placement of mesh in the treatment of stress urinary incontinence to be similar to the placement of mesh for the treatment of hernias?

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A. What I expect is that you cannot divide some particle loss when you're cutting a textile due to the way it is manufactured. Therefore, I expect that you will have some particle loss in both areas. The consequences and quantity -- and quantity may be different.

Q. Do you have an opinion as to in which area the particle loss is greater, whether it be hernia repair or stress urinary incontinence?

A. I think that -- or the particle loss depends on the textile structure of a specific device, whether there are some loose ends that can be released from the material, it depends from the lengths of the cutting, not from the amount of mesh material, but from the lengths of the cutting, the more trimming, the more particle loss you will have. The biological consequences, they have to be defined in relationship to the surgical trauma around.

Q. And my question is: Do you have an opinion to a reasonable degree of

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scientific or medical certainty that the hernia procedure has some degree of particle loss different from what you would expect from placement of mesh for the treatment of stress urinary incontinence?

A. My opinion is from what I've seen from all of the documents that the surgical trauma in hernia repair is much bigger than the application of a sling.

Q. And how does that inform your opinions about the amount of particle loss in either procedure?

A. As I told you, the amount of particle loss depends on the -- can vary between the different devices. It depends from the lengths of the trimming away.

Q. Okay. Doctor, do you know the extent to which a surgeon who implants Ethicon mesh, the TVT® classic, for the treatment of stress urinary incontinence trims the mesh?

A. I'm not an expert of how to handle this during the OR, but at least he cuts it.

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Q. And where does he cut it?
A. He cuts it to remove the needles beneath the skin level.
Q. Does he cut it intra-abdominally or outside?
A. He tear it and cutted it and then it slipped back, but you have to consider that you have a cutting of the mesh during the manufacturing process and, therefore, usually you have these particles there. We all know that there are some during the transport, during the preparation. There are some additional particles that is not necessary that they are released during the trimming process, but particle loss is a concern for textiles in general.
Q. For all meshes?
A. Overall. The amount will differ independent of the type of linkings and connections between the filaments.
Q. When a surgeon implants Ethicon TVT® mesh for the treatment of stress urinary incontinence, the only cutting of the mesh occurs after the mesh is placed, the needles

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are pulled through the skin and then the mesh is cut on the outside of the body; is that correct?
A. The trimming, yeah, outside.
Q. Okay. When the mesh is placed -- strike that.
When a surgeon places Ethicon mesh for the treatment of stress urinary incontinence, after the mesh is cut as you've just described, is the mesh secured to the tissue with anchors in any way, staples or sutures or anything of that kind?
A. No. No.
Q. Doctor, when a surgeon places Ethicon TVT® mesh for the treatment of stress urinary incontinence, what holds the mesh in place?
A. The mesh is kept in place because the surrounding tissue is filling or is -- yeah, is filling the pores of the mesh. So if you are using a sheet without any pores, it will be more easy to remove this. If you have a -- and this is a reason that we use textiles for the reenforcement of the

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tissues because we know that one place in the tissue it is -- it is more difficult to remove them again. Therefore, we had the similar discussions about fixation of meshes in hernia surgery.
Q. So when the surgeon places the mesh underneath the urethra for the treatment of stress urinary incontinence, it's the tissue of the patient filling the pores that keeps the mesh in place?
A. That is my belief, yeah.
Q. Now, do you have any understanding about how the mesh used for the treatment of stress urinary incontinence is placed?
A. I've seen a video.
Q. Okay. And --
A. Or several videos I would say.
Q. Are these -- were you provided videos or did you access them on YouTube or where did you see these videos?
A. Several times on the conferences, videos have been presented there how to do it and there I had the opportunity

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to see this and I got some for this litigation.
Q. From Mr. Anderson?
A. Yes.
Q. Have you seen videotapes showing how surgeons are instructed to use Ethicon TVT® classic mesh for the treatment of stress urinary incontinence?
A. Yes.
Q. What is your understanding about how a surgeon is to place the Ethicon mesh for the treatment of stress urinary incontinence, where and how?
MR. ANDERSON: Objection. Outside the scope of the opinions being offered in this case.
THE WITNESS: I've not the knowledge to discuss any or to give comments to any details of this procedure.
QUESTIONS BY MR. THOMAS:
Q. Do you know how -- strike that.
Do you know the mechanism by which the Ethicon mesh treats stress urinary

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incontinence?
Do you know how it works?
A. I know a lot of ideas that have been developed to get an understanding why this -- why this works and why this doesn't work sometimes. So a lot of ideas to understand this, but I don't know one way how it works.
Q. What's your best understanding as you sit here today about how Ethicon mesh used for the treatment of stress urinary incontinence works?
MR. ANDERSON: Same objection.
THE WITNESS: So far I understood that the sling provides a relaxation of this area at certain strain of the patient so that you have this tendency to -- that you have these changes in the function of the bladder and the sphincters and if you can provide a resistance there by this textile and the -- and the scarring process around this textile.

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QUESTIONS BY MR. THOMAS:
Q. What role do you understand mesh has on the sphincter?
MR. ANDERSON: Objection. Outside the scope of his opinions.
Go ahead.
THE WITNESS: I know that there are several other experts saying that it is not a -- that it shouldn't impact the sphincter at all, but should be in the midurethral area, but it is a huge field and it is not my topic to --
QUESTIONS BY MR. THOMAS:
Q. That's fine.
Do you have any information about how the mesh relates to the bladder for the control of stress urinary incontinence?
MR. ANDERSON: Same objection.
THE WITNESS: Yeah, in general, I have an impression where the sling is, that it's not directly interfering with the wall of the bladder, but, again, this is not the center of my

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work to identify the anatomy or the structures in the pelvic area.
We worked a lot of it, but I'm not prepared to give you a specific analysis of it.
QUESTIONS BY MR. THOMAS:
Q. Can you tell me anything about what the mesh does to treat stress urinary incontinence?
MR. ANDERSON: Same objections.
THE WITNESS: Roughly we assume that with the providence of a nonabsorbable permanent textile structure you have a reenforcement of these tissues around the midurethra, and this is a some sort of counterforce when the pelvis is going down. So, therefore, this is compensating these forces and thereby it improves the situation.
QUESTIONS BY MR. THOMAS:
Q. Do you know mechanistically how mesh used for the treatment of stress urinary incontinence improves the situation as you've

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described it?
A. As I told you, there are a lot of discussions how it definitely works and I just reflect that there are controversials about the definite mechanism, and I cannot provide you the one mechanistic solution.
Q. Do you have any understanding about whether mesh used for the treatment of stress urinary incontinence provides support to the urethra?
MR. ANDERSON: Same objections.
Go ahead.
THE WITNESS: Of course, it supports the tissue area there. It shouldn't be close to the urethra, but, of course, it supports this -- the urethra and this tissue as well.
QUESTIONS BY MR. THOMAS:
Q. You said it shouldn't be close to the urethra.
How close should it be at the most?
MR. ANDERSON: Same objections.
THE WITNESS: If it's very

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close, there's a high risk for erosion.
QUESTIONS BY MR. THOMAS:
Q. Okay. So based on your training and education and experience, how far away should a surgeon place the mesh in order to protect against erosion?
MR. ANDERSON: Same objection. His experience -- training, education and experience, as he has told you, has nothing to do with the treatment of SUI.
THE WITNESS: I have no experience to give you some comment on this. I know it is a problem for the surgeons doing this procedure.
QUESTIONS BY MR. THOMAS:
Q. What's a problem?
MR. ANDERSON: Same objections.
THE WITNESS: That in some patients you have a damage of the urethra later on.
QUESTIONS BY MR. THOMAS:
Q. Do you know in what percentage

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of patients that happens in the placement of mesh for stress urinary incontinence?
MR. ANDERSON: Same objections.
THE WITNESS: No, not -- I don't recall. I've read it, of course, but I don't recall in the moment.
QUESTIONS BY MR. THOMAS:
Q. Do you know from your research in this case where relative to the urethra the surgeon is instructed to place the mesh?
MR. ANDERSON: Same objections.
THE WITNESS: I know this from the video, what is said there, but I've not the expertise to do this procedure or to give a comment on this.
QUESTIONS BY MR. THOMAS:
Q. What do you recall from the video about the placement of the mesh relative to the urethra?
MR. ANDERSON: Same objections.
THE WITNESS: That it should be placed right and left to this and

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there has to be a distance. So I'm not able to recall and to replay the video and I didn't never tried to do so.
QUESTIONS BY MR. THOMAS:
Q. Do you have any understanding about whether the mesh -- strike that.
Do you have any understanding about whether the Ethicon TVT® mesh used for the treatment of stress urinary incontinence is designed to provide support for the urethra?
MR. ANDERSON: Same objections. He's not being offered as a urogynecologist or a urologist.
Answer his question, if you can.
THE WITNESS: I only have a very limited -- no, I -- if you address that problem whether it's designed for the use as a sling, I cannot remember very good -- no, I cannot remember in the documents that there was a specific design for this

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purpose that is used for the reenforcement of this area. As I told you, yes, there is a risk of the damage of the urethra, yes, by the surgeon immediately, that is one sort of damage.
The other is after two or three years you may have this damage and this is a problem with the material. So these are -- has to be separated in this discussion that the mesh material is specifically designed for this purpose. I don't get any data that confirms this.
QUESTIONS BY MR. THOMAS:
Q. Doctor, let's go to page 28 of Exhibit 11.
Page 28 of Exhibit 11 deals with that portion of your opinion that addresses mesh contraction.
On page 29, you have a Figure 7 which is a photograph of a mesh explant.
Is that a hernia mesh explant?
A. It is a mesh that we used in

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hernia.
Q. What kind of mesh is that?
A. I have to recall. It's either Prolene® or it's Marlex. I guess it's Marlex. I know it's written in the document, but I don't recall it.
Q. Okay. On page 30, Figure 8, again, Figure 8 is a hernia mesh?
A. Yes.
Q. And do you know what kind of hernia mesh that is?
A. It is a composite of polypropylene and the ePTFE.
Q. And who makes that mesh? Is it called a Kugel mesh?
A. Kugel mesh.
Q. And that's a BARD product?
A. I think so, yeah.
Q. And Figure 9 A, that's an explanted Prolift® mesh that apparently you've taken from the International Urogynecological Journal; is that correct?
A. Yes.
Q. And Prolift® mesh is a

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different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?
A. Yes.
Q. It's called Prolene® Soft?
A. Yes.
Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos.
Is that correct?
A. Yes.
Q. Did you ever observe other than by photographs the actual explant of Carolyn Lewis?
A. No.
Q. So do you have other photographs of the mesh explant in addition to the one that's in 9 B?
A. I do not recall.
Q. Did you make any effort to use the photograph in paragraph 9 B to analyze the condition of the mesh?
A. No. And I'm convinced it is not possible to make any further analysis

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from this image.
Q. Okay. Why?
A. The placement of these mesh particles, it depends from how it -- what happens during the OR, how it's done, how it's taken, how it was handled. There's no protocol how to handle all of these mesh materials there to remove this so, therefore, every further finding when you try to measure something here, it will be very hard to impossible to get a good interpretation of this.
Q. It's fair to understand that after a mesh is explanted, a person needs to know how the mesh is handled at every step before your analysis so that you can understand the extent to which the explant may have been altered, fair?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: It depends from the question you further on have.
If you just want to know if there are some specific cells at the

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interface, it is not important to know where it's explanted or so.
So it very -- it depends from where you're looking at whether this is affected by the handling of the surgeon.
QUESTIONS BY MR. THOMAS:
Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?
A. Cut in sections, in histological sections?
Q. Yes.
A. The fact that I was provided only the histological cut that gives some limitations to the analysis, of course. So you are restricted to what you see there.
Q. Other than the image that's on page 31 of your report and the histological cuts that you've just described, were you provided any other information related to the explant of Mrs. Lewis?
A. I've seen the report during the

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operation by the surgeon.
Q. Okay.
A. And the pathology statement from the hospital. So some medical records.
Q. Other than the operating room report and the pathology report from the hospital after the explant, do you recall receiving any other information about Carolyn Lewis?
A. Yeah, I recall 10, 11 files with medical records to various extents and thousands of pages with lab results and post-analysis and --
Q. Okay. Did you understand that you received, to the extent that it was available, her medical history?
A. Yes.
Q. Okay. So is it fair to conclude, Doctor, that you didn't analyze the mesh that's on -- in the photograph on Figure 9 B on page 31 of your report to determine the extent to which the mesh contracted?
MR. ANDERSON: Objection.

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Go ahead.
THE WITNESS: I didn't analyze it on the basis of this microscopical image.
QUESTIONS BY MR. THOMAS:
Q. Do you have an opinion to a reasonable degree of scientific certainty that Ethicon TVT® mesh used for the treatment of stress urinary incontinence contracts after implantation?
A. To make it clear in advance, I know that polymer itself does not contract and polypropylene does not contract itself. It is contraction of the wound area. It's a contraction of the collagen. It is a change of the tissue there. To be clear in this field, otherwise everyone can say a plastic sheet doesn't contract.
So in this regard that the scar shows some contraction and with this scar contracts the mesh, yes, it depends. In principle, the extent of contraction is related to the extent of scar formation and Prolene® induces a lot of scar formation and,

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therefore, yeah, you have a high risk for shrinkage and contraction. We know -- to say it already here, we know that there are some patients where it's less and there are other patients where it's more pronounced.
But what we have learned in these 20 years is that Prolene®, with its structure, with its weight, with its amount of material, it's a high risk for contraction.
QUESTIONS BY MR. THOMAS:
Q. In your 20 years of research, have you specifically studied the extent to which Ethicon Prolene® mesh used in the treatment of stress urinary incontinence contracts in vivo in the stress urinary incontinence application specifically?
A. We did not make our preclinical experimental studies to this topic, but I know that my clinical colleagues made some ultrasound investigation looking into the slings that Dr. Tunn in Berlin has done it, that there is -- there are some references showing that you can -- that you can analyze

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the degree of contraction in patients as well and that you find there some narrowing of the width of the sling.
Q. Have your clinical colleagues published any study describing their experience of contraction?
A. There has been a presentation, I think, at an international Congress and at the -- at a German conference where they presented their results.
Q. Do you know if the results that your clinical colleagues found have been published anywhere outside of this presentation?
A. At least the European or the international abstract has been published in the supplements there.
Q. Who are your colleagues so if I wanted to find that abstract I could find it?
A. Professor Kirschner-Hermanns, was a coauthor, Dr. Najjari, she made the study.
Q. Do you cite that abstract in your report?

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You know, I don't need to know.
You mentioned some work by Dr. Tunn in this area.
A. Dr. Tunn, yeah. We call it -- he has published studies using ultrasound looking what happens to meshes there, and I think it was -- it were one of the first articles published showing that there is this change of the mesh structure which was quite common in hernia surgery, we know it ten years longer, but for the urogynecologists, it was a new message at that time, I believe.
Q. Now, was his study published in a journal?
A. It was published in a journal. I don't recall precisely whether he was focused on meshes, the flat meshes, the Prolift® things, or whether he really looked to the slings or whether he combined it. I don't recall the details any longer, but he showed very clearly that using a textile in the pelvic floor as well you have these changes what we have seen in hernia surgery years ago.

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Q. Do you recall the extent to which Dr. Tunn found contraction in the study that he conducted?
A. Significantly. 50 percent or more.
Q. And when you say "50 percent or more," does that mean that the tissues surrounding the mesh basically shrinks in half?
A. That is a good point because there is a mixup of all of these things. Whether it's a reduction of the area of 50 percent, then you have a smaller reduction in the lengths and in the sides. So sometimes they -- in the literature, it's -- they mention the reduction of the lengths, not of the area.
So it is very often not clear about it, but at least in our clinical study, they measured the widths of the sling so it is clear it is in one dimension.
Q. Okay. Now, on page 33 of your report, in the middle of the page it says, "It also is my opinion to a reasonable degree

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of medical and scientific certainty that the Prolene® mesh in Ethicon's TVT® products contracts or shrinks 30 to 50 percent after implantation.
Is that correct? Did I read that correctly?
A. Yes.
Q. Does that mean that every mesh implanted in a woman for the treatment of stress urinary incontinence is going to shrink at least 30 percent?
A. No, that is -- that is not -- that is not correct. I wouldn't expect this. We know that from all of these preclinical and clinical studies that has been done to address the issue of shrinkage, it, of course, is influenced by the textile structure, but it is influenced by the surgical trauma as well, which leads to scar, which leads to a contraction of this area.
So even the best mesh which probably does not induce any inflammation in this field will be in an area of scar that shows a contraction of about 15, 20 percent,

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if you have extended scar tissue. If you have a laparoscopic procedure where the surgical trauma is minimized, this can be less than 20 percent. When you have an open surgical trauma there, it should be in around 20 percent. I would expect that this is a range that will be very hard to come below this range.
Q. For any --
A. Everything -- yeah, it is a consequence of the surgery and of scar. If you create some scar, you have it. If you produce a lot of scar, this shrinkage rate can go up to 80 or 90 percent.
Q. And when you use figures in your report of 30 to 50 percent or use numbers like you just used a moment ago of 80 to 90 percent shrinkage, what does that mean?
MR. ANDERSON: Other than what he's already told you?
MR. THOMAS: Well, he told me there's a confusion in the literature about how it was measured and I want to know what he means.

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MR. ANDERSON: Well, he told you more than that, but go ahead.

THE WITNESS: So we started when we first made revision operations and looked to all of these old meshes. We took a lot of photographs where we took the images of the mesh when it was implanted, we got a size of it and then later on at the revision you see that only a small -- a much smaller mesh because of the contraction. And that was the extent of shrinkage at that time.

Amid at the Suvretta meetings, he reported of a shrinkage rate of 80 to 90 percent for the plaques which are very big amount of material in a small place so this is the upper limit 80 to 90 percent of this. When we made our own experiments where we tried to figure out and we were still busy to work on it to objectify the extent of the shrinkage under various conditions.

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QUESTIONS BY MR. THOMAS:

Q. Are you currently involved in a study analyzing the extent to which the tissue around mesh shrinks or contracts?

A. Yeah. We have a study in the groin to look what happens to the mesh material after one year and specifically with the focus on shrinkage.

Q. Okay. And we talked about that yesterday?

A. Yeah.

Q. Have you ever conducted a study to determine the extent to which the tissues surrounding mesh after implantation for the treatment of stress urinary incontinence contracts?

A. We did a lot of these studies with Prolene®, with Marlex, which is the mesh that is used for the treatment of.

Q. I'm talking -- I am sorry.

A. But we didn't make specific analysis which reflects the treatment with a sling in the pelvic.

Q. Okay. So is it fair to

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understand that based on your training, education and experience that the use of mesh in any application will induce a shrinkage or contracture of 20 percent?

A. Not in the meaning that the mesh makes a shrinkage of 20 percent. It depends from the type of mesh. There are some meshes which usually lead to shrinkage that is 30 to 50 to 60 to 80 to 90 percent so.

Q. I get that.

My question is: Is the best that you can do when you use mesh in the human body is to have a shrinkage or contracture rate of 20 percent?

MR. ANDERSON: Objection. Asked and answered.

Go ahead.

THE WITNESS: As I told you, it depends. It's influenced by the surgical trauma as well. If you have a very, very small surgical trauma and very little scar formation, there may be. I can't imagine that you can go

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below this range.

QUESTIONS BY MR. THOMAS:

Q. "This range" being what?

A. Of 20 percent but, yeah.

Q. Okay. In how many patients who receive Ethicon TVT® products do you expect to see a shrinkage rate of 30 percent?

A. You cannot answer. It depends from the time period. It depends from the conditions of the OR. It depends whether there is a contamination with bacteria. It depends from the degree of the inflammatory process. So hopefully the number is quite low, but even if it's low, if it's not necessary, it should be avoided.

Q. In how many patients who receive Ethicon mesh for the treatment of stress urinary incontinence would you expect to see a shrinkage or contracture of 50 percent after implantation?

A. I can't give you a figure.

Q. Is that a common finding, a rare finding? Do you have any kind of range at all to attach to that number?

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MR. ANDERSON: Objection as to form.
Go ahead.
THE WITNESS: Again, it depends from the subgroup which you analyze and the time period. If you're looking after two months, then you will not expect a significant shrinkage due to wound contraction and therefore, the function may be very well.
If you're going to -- if you're looking at two years, three years and you have a patient with increased problems in this area due to the scarring process, then the likelihood of finding a shrinkage is -- well considerably higher.
If you look to all of the patients that you are -- you have to think about in the moment. In this subgroup, I expect that the rate of the significant shrinkage is much higher than in those who doesn't have

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any problems.
QUESTIONS BY MR. THOMAS:
Q. Doctor, is it fair to understand that mesh shrinkage or contracture does not always lead to patient complications?
A. I would expect that there isn't a hundred percent correlation between shrinkage and complaints. However, what we have learned in all our work is shrinkage is another description of reality. It's an explanation of complaints in many patients.
Q. And when you performed hernia surgery, you understood that your mesh would shrink or contract, fair?
A. I expected a shrinkage of this area to some degree in every patient, yes.
Q. And the extent to which that shrinkage or contracture caused any complication in the patient depends on the surgeon's skill and the specific comorbidities of the plaintiff -- excuse me, of the patient; is that fair?
MR. ANDERSON: Objection.

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THE WITNESS: No, it doesn't depend on it. It is influenced on. So you can create some pain just by surgery. You don't need a mesh to create some pain. But if you have an excellent surgery, excellent patient and then you get a pain, then maybe it can be a problem of the mesh.
QUESTIONS BY MR. THOMAS:
Q. Well, my point is you discuss with the patient who is considering whether to have mesh implanted for hernia the fact that this mesh will contract and it may cause complications?
A. Yes, but we are able to tell them that we are using mesh material where this risks has been minimized.
Q. Okay. And to the extent that you're using a heavy-weight, small pore mesh for those repairs where still appropriate, you would have the same conversation, wouldn't you?
A. Similar conversation, but another list of risks and benefits.

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Q. What are the complications that you associate with shrinkage?
A. Shrinkage?
It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to the physiological requirement or physiological characteristics, properties of the surrounding tissue, it became a very stiff thing and, therefore, it causes complaints and pain just by restricting the mobility of the tissue. It expresses huge intensity of scar formation in this area so there is a high risk of getting entrapped nerves in this scar formation. It reduces the area of the mesh material. In the field of hernia surgery, you expect that the overlap is decreased and, therefore, the increase for recurrence is higher.
If you have a significant shrinkage for meshes, slings that have to

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withstand some forces, then you have a higher pressure to the cells because the contact area is reduced. Shrinkage means that you have an accumulation of material at a specific area so even the large pore constructions will change and switch to small pore constructions. This may be some.

Q. Do you have any idea of the rate of complications that are reported due to contracture or shrinkage in the placement of mesh for the treatment of stress urinary incontinence?

A. We had some figures where we can -- where we can estimate the increase of risk for pain for these heavy-weight, small pore meshes as Marlex, as Prolene®, which were used for the treatment of incontinence.

Q. Marlex is not used for the treatment of stress urinary incontinence, is it?

A. As these meshes that are used, Marlex, no, it's not used. But these are -- these are the group of meshes and Prolene® is one of the meshes that is used.

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I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.

Q. I'm talking more specifically than pelvic floor. I would like to know for the treatment of stress urinary incontinence whether you have any idea of the rate of complications that are reported due to contracture or shrinkage in the placement of mesh for the treatment of stress urinary incontinence?

MR. ANDERSON: Objection. Asked and answered.

Go ahead.

THE WITNESS: Independent from the mesh material, if you wanted to know some figures of the patients treated for incontinence, whether they have some problems, I can't give you

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the figures.

QUESTIONS BY MR. THOMAS:

Q. Okay. Doctor, do you have an opinion about the extent to which mesh contracture or shrinkage in patients who are being treated for stress urinary incontinence impacts the cure for stress urinary incontinence?

MR. ANDERSON: Objection to form.

THE WITNESS: It depends from the subgroup you're analyzing. If you're analyzing the patients that complains afterwards, you will find a significant ratio of patient that suffered from shrinkage and, therefore, developed these complications.

QUESTIONS BY MR. THOMAS:

Q. When you say "complaints," what kind of complaints are you talking about?

A. Pain, dysfunction of the bladder.

Q. Now, just so --

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A. Erosions.

Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair?

A. What?

Q. Strike that.

The treatment of stress urinary incontinence is designed to treat the involuntary discharge of urine?

A. Yes.

Q. With that goal of the treatment in mind, does mesh contracture or shrinkage have any impact on the ability of the mesh to treat that condition?

A. Shrinkage, from my opinion, will be one reason or is a fact that reflects the extent of scar formation and this will be one reason for bad results of this procedure.

Q. And when you say "bad results," in terms of the ultimate goal of treating the stress urinary incontinence, what would you expect?

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MR. ANDERSON: Objection to form.
THE WITNESS: I didn't -- I didn't understand what comparison you want to have.
QUESTIONS BY MR. THOMAS:
Q. Well, we understand the goal of using mesh to treat stress urinary incontinence is to manage the involuntary discharge of urine, correct?
A. Yes.
Q. If you have mesh contracture or shrinkage, how does that impact what the mesh does to treat the involuntary discharge of urine?
A. If you have a significant shrinkage, a significant scar formation in this area, then you can have pain, you can have a increase -- or migration and erosion of the urethra. You can have erosion in the vagina.
So all of these things can be the consequence of scar formation and shrinkage in this field.

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QUESTIONS BY MR. THOMAS:
Q. Do you know whether mesh contracture or shrinkage impacts the ability of the patient receiving the mesh to control her urine?
A. I didn't -- please rephrase it.
Q. Do you know whether mesh contracture or shrinkage controls -- strike that.
Do you know whether mesh contracture or shrinkage impacts the ability of the patient receiving the mesh to control her urine?
A. I expect that considerable shrinkage of the mesh can in some patients lead to the -- or to a recurrence of the incontinence.
Q. Okay. So you would expect the incontinence to return. Mechanistically, how does that happen?
A. I have the impression that we're back some two hours ago. There is a complex interaction between the ligaments, the muscles of the pelvic floor. It's a very

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complex system, and if you have a very strict scar there that may be too small, that this impairs the dynamic of the pelvic floor significantly and, therefore, the function of all of the organs that are in the pelvic floor.
MR. ANDERSON: It's my turn to take a break.
MR. THOMAS: Sure.
(Off the record at 11:23 a.m.)
QUESTIONS BY MR. THOMAS:
Q. Doctor, during the development of VYPRO I, did you have any involvement in the biocapability analysis of VYPRO I?
A. Yes.
Q. And were there tests conducted on VYPRO I for carcinogenicity, for example?
A. If you think -- if you're thinking of some in vitro tests for -- I do not recall whether these tests have been done in Aachen.
If you're thinking of the general discussion about whether there is a risk for cancer when using textiles, we made

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investigations.
Q. Okay. Did you make investigations -- strike that.
Do you recall conducting any in vitro testing for VYPRO I?
A. In vitro testing we did it for the attachment of bacteria. We did it for the -- for the -- we did it in a setting where we looked what happens to the fibroblasts when growing together with meshes in vitro. That has been our studies, yeah.
Q. Did you conduct any cytotoxicity testing for VYPRO I?
A. Not that I recall.
Q. Do you recall learning that VYPRO I tested positive for cytotoxicity in vitro?
MR. ANDERSON: Objection. Based on his prior answer.
Go ahead.
THE WITNESS: I recall that somewhere in the documents there has been some -- there has been done some in vitro cytotoxicity tests indicating

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that polypropylene has some problems, but I do not recall any specific investigations to the VYPRO that is done in Aachen. I'm sure it will be done or it was done in Hamburg Ethicon because it's required before launching a product to the market.

QUESTIONS BY MR. THOMAS:

Q. And my question is simply this: Whether you did the testing or not, did you ever learn from any source that VYPRO I tested positive for cytotoxicity in vitro during the biocompatibility analysis?

A. Not that I recall.

Q. About an hour ago, maybe more, you mentioned a recent study in the last year involving PVDF mesh and I thought I understood you to say it was a comparative study.

Do you recall that testimony?

A. I mentioned a study with PVDF?

Q. And I want to say, my notes are very sketchy on it, I tried to write it down so I could remember, but I thought it was a

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comparative study involving PVDF meshes perhaps out of Berlin.

MR. ANDERSON: He's asking you if earlier in your testimony did you -- were you talking about some comparative study involving PVDF meshes out of Berlin.

THE WITNESS: In the pelvic floor?

QUESTIONS BY MR. THOMAS:

Q. Anywhere. Pelvic floor, hernia, I'm not sure.

A. Comparative in the meaning that you compared different materials and one of it is PVDF?

Q. Yes.

A. No, I don't recall any clinical study.

Q. Okay. Since your deposition last year, are you aware of any clinical studies that compare the risks and complications associated between PVDF and polypropylene?

A. Now I got it. You may refer to

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this study that is done by our gynecologist, Dr. Najjari, who made ultrasound investigation comparing two different slings, one of polypropylene and one of PVDF, and they presented these results in this abstract that has been published in this supplement article.

Q. Other than that study that you just described, since your last deposition in October 2012, are you aware of any clinical studies that compare the use of PVDF to the use of polypropylene in any application to determine which is better?

A. No, I don't recall any clinical study.

Q. Doctor, what have you done to analyze the forces that are placed upon mesh used for the treatment of stress urinary incontinence?

A. It started with our efforts to get a first impression about forces to the mesh materials in principle, how to define it, how to measure it, how to get a range, a figure out, and these efforts started in 1993

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with this question. And in 1994, we started to think about how to define the forces, the requirements to the textiles for the reenforcement in tissues.

So that was the -- that is the rough experience that we got during all these years that we got an impression of the range and what can be considered as over engineered and whatnot.

In 2005, '6, the upcoming question was what are the biomechanical properties to the pelvic floor and we tried to -- or we made -- we looked very careful to the literature, Cosson and all of these expressed what they are considering for the use in the pelvic floor and so we tried to combine all of this knowledge to get an impression.

Q. Okay. So what specifically have you done to analyze the forces that are placed upon mesh used for the treatment of stress urinary incontinence?

A. As I tried to answer it before, we analyzed a lot of these data that have

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been there. We analyzed very careful the difficulties to find a good equipment, a good setting, to come to a specific data there. And finally we got an impression about the biomechanics, the differences of the biomechanics between the pelvic floor and the abdominal wall. We didn't do any specific measurements as Cosson did, yeah.

Q. When you're talking about forces in the pelvic floor, are you talking about forces that occur in the pelvic floor in the management of pelvic organ prolapse?

A. It is not limited to the pelvic -- it is not limited to the prolapse. It is -- when we have been studying the biomechanics of the pelvic floor, what happens there, the intention of this was to define what may be the requirements of the textile in regard to stability. That was the purpose for this. Not to simulate or to reflect the situation there and, therefore, we focused mainly on some forces per centimeters and, yeah, we know that there are -- or I know that there is a -- that it's

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very difficult to define really the biomechanics in the pelvic floor. It is impossible to get all aspects there.

So force is one aspect, but we focused on the force -- what is important for the characterization of the mesh material, of the textiles there.

Q. And what forces did you study to determine the requirements for textiles in the pelvic floor, what forces did you study?

A. The forces -- the basis of our -- of my opinion about the -- it is based on the experience that tissue has some limited ability to withstand some forces so any repair has to consider that the surrounding tissue is limited in this field.

You have to consider some intraabdominal pressure, that you have to consider some flexibility of the anatomic structures. We have made some measurements tearing out looking at what is the resistance of tissues to extract meshes or sutures or anchors what are the forces there. We made some analysis of textile structures, what are

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forces, what is elasticity that can be done there.

So a lot of various things to get a closer idea about the biomechanics of the pelvis.

Q. What specifically have you done to measure the forces that are applied to mesh that are used for the treatment of stress urinary incontinence?

A. We never made direct measurements of the forces.

Q. Have you reached any opinions about the nature and the extent of the force that's applied to the mesh used for the treatment of stress urinary incontinence?

A. So in conclusion of all these -- our experiences and all of the literature there, it is -- it is -- I'm sure it is in a range that is far below the tensile strength that is required for the abdominal wall so it is less about 10 newton per centimeters. Yeah, less than 10 newton per centimeters I would expect.

Q. And when you say 10 newtons per

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centimeter, what does that measure?

A. That means that's the force per centimeter of the textile. I know there's a mixing up, and I recall a very precise summary of this mixing up by Professor Williams. At the last deposition, he made an expert report where he summarized the mixing up of pressures force per centimeters and forces, per se. That cannot be interfered or that cannot be exchanged so this figure is limited to newton per centimeter, that means per centimeter of mesh in the width end or tissue.

Q. And when you speak about force, in what direction is it applied?

A. It's a uniaxial force.

Q. And from what direction is it applied?

MR. ANDERSON: Objection to form.

THE WITNESS: It is a -- first of all, it is an abstract direction -- yeah. No, it's theoretical assumption without having a specific direction.

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When you estimate the tensile strengths that is necessary to reinforce abdominal wall of the pelvic floor, there is no specific direction. If you made a measurement at the textile, indeed you have to make separate analysis in meshing direction and perpendicular to the machine direction then you will get different results.

But to define the -- an estimate of the maximum of the requirement -- maximum or minimum requirements, then there is no direction.

QUESTIONS BY MR. THOMAS:

Q. Okay. You said a moment ago that the force was uniaxial.

What do you mean by that?

A. Uniaxial is the experimental setting that you fix the mesh or the sample -- tissue sample or mesh sample on one side and your tearing on the other and then you get a force. And if it's a stripe with

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widths of 1 centimeter, you get some figure. If it's 2 centimeters, you get another figure.

To easy up the comparison of different structures, later on it is normalized to a width of 1 centimeter, though, in fact, these measurements are all done at various widths of the sample size, 4 centimeters, 5 centimeters. There are different standards. Usually it's described in the material and methods.

Q. And the uniaxial testing you're describing now, is that used by yourself and Dr. Mühl in your study, Exhibit 20; is that correct?

A. This uniaxial testing is part of these measurements of Professor Mühl, but we started in 1994 with our first textile analysis to provide this data.

Q. Back in 2008, 2007, when Exhibit Number 20 was published, the last sentence of the abstract says, "Further, in vivo studies have to investigate whether the preservation of a high effective porosity

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under stress may help to improve biocompatibility of textile implants."

Has there been any further in vitro -- have there been any further in vivo studies to investigate whether the preservation of a high effective porosity under stress may help to improve the biocompatibility of textile implants?

A. Can I have a look?

As we discussed yesterday, the -- a difficult or an important point is to identify the impact of these effective porosity on the clinical outcome, how to identify this. And, yes, indeed there -- we meanwhile know that there are various mesh materials. We try to get precise data of the effective porosity of the various kinds of materials and we want to analyze registries in regard to these properties of the mesh materials. These are the studies we're working on in the moment. So, yes, there are attempts to make clinical studies.

Q. But there haven't been any published yet --

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A. No. No. No.

Q. Let me get my question out.

A. Yes.

Q. There haven't been any studies -- strike that.

There haven't been any in vivo studies which investigate whether the preservation of a high effective porosity under stress may help to improve the biocompatibility of textile implants; is that correct?

A. Yes.

Q. Now, we talked earlier about how the mesh is placed in the body.

It's not anchored or secured on either end?

A. That is correct.

Q. And the way the mesh holds its position in the body is by the tissue moving through the pores and anchoring the pores, correct?

A. If you restrict it to the time period directly after the operation, this is for the first seconds or minutes, this is the

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major mechanism, I suppose. Later on, it will be replaced by others.

Q. When there are forces applied to the mesh after implantation, the mesh can move with the forces, can't it?

A. If you apply some forces to a mesh, then, first of all, you have some sheering stress at the area where the forces is applied.

So the assumption that the entire mesh as a block moves accordingly to some forces somewhere, I think this is not a true, realistic image.

Q. Okay. In hernia repair, you often anchor the mesh, suture it; is that fair?

A. Fixation of meshes for incisional hernia, it is not necessary. When you place a mesh in the retro muscular position, it is not necessary to do any fixation anymore. If you make a TP repair and you place a mesh there, there's no need for making any further fixation there. If you make a TAPP, you increasingly use glue --

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which Fibrin glue from Ethicon, for example, that sticks there or fixed there the mesh for some days or hours. So short-term fixation there.

It depends on the position. It depends -- IPOM mesh usually have to get a fixation. It is a -- yeah, it is a difficult question there.

Q. Okay.

A. It depends on the mesh and on the localization on the patient, on the surgeon.

Q. Uniaxial loading means just as you described it. You have one end of the mesh stable and you pull the other end, correct?

A. It's not necessary that one end is stable even if you have a textile like this and you're tearing from both sides, it's uniaxial.

Q. Okay. And what are the forces underneath the urethra that cause the uniaxial loading that you've just described?

A. To my knowledge, there isn't

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any precise measurements of this that does not interfere with the -- with the procedure.

In general, you have to expect that by the movement of the urethra, by some physiological movements, standing up or pressing or so, or the movements of the pelvic floor, that you have some shifting of the position of these -- of these organs in relation to other -- to the bony structures.

And this shifting, this mobility, this movements, they will lead to some locally forces.

Q. And those forces will come from multiple directions, won't they?

A. Always. Always they will come to -- from all directions, from all three directions, but to get a good estimate to get an idea of the model to evaluate a device or to construct a device, I am sure that for slings it is a reasonable and acceptable compromise to think that the uniaxial is more important.

Q. And on what do you rely for that statement?

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A. On our experience, the literature.

Q. In hernia repair?

A. Textile. Not hernia repair. It's a use of textiles for the reenforcement of tissues.

Q. Okay. Specifically, Doctor, have you analyzed the forces that are present in the area of the body where the mesh is placed for the treatment of stress urinary incontinence?

A. Whether I've analyzed these forces?

Q. Yes.

A. Only in the way that I try to express looking to the literature, looking to -- making some measurements at textiles to see whether it's comparable or not.

Q. Can you point me to any literature or research upon which you rely specifically identifying the forces that are present in the area where the mesh is placed for the treatment of stress urinary incontinence?

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A. I recently found a publication from 1995, I guess, where they placed at the time before TVT®, they -- at the time, they placed fascia slings around the urethra and there they measured the force there.
Q. Do you remember the name of that study?
A. Not at the moment.
Q. Did you find that information to be valuable, important to you?
A. It was just recently that I found it, but it was a confirmation of these estimates.
Q. Okay.
A. Because it was less than these 10 newtons.
Q. And do you recall what that study that you found looked at and what it found?
A. They measured in patients with a device the force at both sides of these fascia sling that the force that was necessary to make a narrowing of the urethra.
Q. Okay.

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A. So they got an in vivo force there.
Q. Okay. So anything other than this 1995 study that you recently reviewed upon which you rely for the forces that are present in the area of the body where mesh is placed for the treatment of stress urinary incontinence?
A. Look to a lot of these references, but from my memory, the Deprest working group with Ozon -- I think Ozon is his name, they presented two, three extended thesis, documents where they presented a lot of data, what they measured and what they calculate, what they estimate.
Q. Okay.
A. For the pelvic floor area.
Q. Okay. Now, did -- is Cosson, is that what you said or Deprest?
A. Yeah, Cosson made a lot of measurements at the tissue, but it was from Leuven, Deprest, yeah. This working group there.
Q. The working group that you just

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described, did they provide any measurements of the forces in the body at the place where the mesh is used for the treatment of stress urinary incontinence?
A. They made some -- as I recall, they made some estimates of the tensile forces that should be considered for the reenforcement of pelvic floor area.
Q. Now, I'm not talking about reenforcement of pelvic floor.
I'm talking very specifically about mesh placement for the treatment of stress urinary incontinence.
A. I don't recall that they have a specific chapter dealing with slings.
Q. Okay. So we're back to the 1995 study.
Is there any other study to which you can point me in support of the -- your understanding of the forces in the body at the place where the mesh is used for the treatment of stress urinary incontinence?
A. There maybe -- maybe some others, but I don't recall. But these --

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this is -- to my knowledge, this is the only one who really measured the forces.
Q. And just so the record is clear, you have not conducted your own analysis of the forces in the body at the place where mesh is used for the treatment of stress urinary incontinence; is that true?
A. That is true, I didn't do it.
Q. Okay. Now, when you use the term "uniaxial loading," you were referring to forces purely coming from one end to the other of the mesh; is that correct?
A. That is correct.
Q. Seems to me that if mesh is placed across a woman to support the urethra for the treatment of stress urinary incontinence, that there will be forces from the back to the front of the mesh as well; is that true?
MR. ANDERSON: Objection to the form of that question.
THE WITNESS: If you're talking about forces that happens in the pelvic floor area, you're right.

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There are various forces for the various structures.
QUESTIONS BY MR. THOMAS:
Q. So the basis of your opinion is that the predominant force is uniaxial; is that fair?
A. In a sling, the assumption that the uniaxial force is an important issue, yes, that is true.
Q. Okay. How does the body apply a uniaxial force to a sling?
A. If you place -- in contrast to meshes which are flat meshes with a wide area of tissue integration, when you make small slings, not 20 centimeters, but 1 centimeter, and this is 20-centimeter long there and you made or placed a sling from the lower part of the pelvis to the skin there, that if you have some movement there in this direction --
Q. You're moving down?
A. Down, yeah.
If the pelvic floor is going downwards, I expect that most of the forces, the strain, is going in the similar direction

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where the sling is located. And if you compare the movements going down, they are -- or they are in relation to the widths of the textile, they are -- they are higher than the mobility in these two directions.
Q. Okay.
A. You only have 1 centimeter of width. If you have a tensile force trying to make this wider, it's a very small effect.
Q. Okay. So as I understand your answer, please correct me if I am wrong, a downward force perpendicular to the placement of the mesh will cause a uniaxial loading on the mesh; is that correct?
MR. ANDERSON: Objection to form. Mischaracterizes his testimony.
THE WITNESS: What I wanted to express is that you place a sling, that the uniaxial strain to this sling in the direction of the sling, that is more relevant than the strain from the sides.
QUESTIONS BY MR. THOMAS:
Q. Okay. Uniaxial loading by

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definition means you're pulling on each end, correct?
A. Or you made a fixation at one end. It is uniaxial, it is just in one direction.
Q. And the force that you just described, if you have a mesh in a straight line, the force that you're describing comes from above is down on top of the mesh; is that correct?
MR. ANDERSON: Objection. Form.
THE WITNESS: However -- the result is that the sling, the ligament, is stretched.
QUESTIONS BY MR. THOMAS:
Q. I understand.
A. And that makes an uniaxial strain.
Q. But the force you're describing is not at the end, it's from the top down on the mesh, correct?
A. Yes.
Q. And so when the force comes

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down on top of the mesh, there is a force into the pore structure of the mesh, correct?
MR. ANDERSON: Objection.
Do you understand his question?
THE WITNESS: Yeah. Yeah, but I just -- in principle, yes, there's force, but what is the force, how big is the force. It depends on the surface, it depends from the cells. As a scientist, I usually try to then to measure it. I think it is impossible. There is a force, yes, but I think it is -- I'm sure it is a -- in an area where it's almost impossible to measure because it's so low.
QUESTIONS BY MR. THOMAS:
Q. Let me ask you this question, Doctor.
A. And, therefore, not relevant so --
Q. Can you think of a circumstance in the body where a mesh used for the treatment of stress urinary incontinence is

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placed under stress by pulling one end against the other like you do in Exhibit 20?
A. Is placed under stress?
Q. In the same way that you did in the study which is Exhibit 20.
A. So far I understood is that the recommendations when implanting these slings, that this shouldn't be done by applying a huge amount of tension there. And I don't think that it's a good idea to place a mesh wherever under tension.
Q. So my question is this, Doctor. I'm trying to understand whether you can identify for me any force in the body that is uniaxial in nature that replicates the forces that you and Professor Mühl used in your study, Exhibit 20.
MR. ANDERSON: By that you mean uniaxial forces?
MR. THOMAS: Yes.
MR. ANDERSON: Okay.
THE WITNESS: Whether I can identify these forces?

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QUESTIONS BY MR. THOMAS:
Q. Yes.
MR. ANDERSON: He said anywhere in the body where there are forces that are uniaxial, right?
MR. THOMAS: Okay. Let me ask the question again.
MR. ANDERSON: It's a little confusing. Yeah.
QUESTIONS BY MR. THOMAS:
Q. My question, Doctor, is this, I think: Can you describe for me forces in the area where mesh is placed for the treatment of stress urinary incontinence that replicate the forces that are used by you and Dr. Mühl in your study of effective porosity, which is Exhibit 20?
A. The first issue is whether there are some uniaxial strain there and if you look to the anatomy, you have some ligaments. Ligaments usually are thought to compensate uniaxial the mechanical strain, the biomechanics there, in contrast to some fascias or muscles there.

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So any procedure using textiles for the replacement of ligaments usually mainly has to address uniaxial forces. So textiles replacement of ligaments usually I think it is -- very acceptable to reduce this to an uniaxial model.
Q. Ligaments have forces and stresses in other directions, too, don't they?
A. As we told, there are always forces to some degree from every direction, but they are not significant. They are not relevant in comparison to the others. That's a reason that you have ligaments and not a muscle at that position.
Q. And my question, Doctor, is can you describe for me specifically those forces in the area where mesh is placed for the treatment of stress urinary incontinence that replicate this uniaxial loading?
MR. ANDERSON: Objection. He just answered it.
MR. THOMAS: He used a ligament as an example.

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MR. ANDERSON: Yeah.
THE WITNESS: If you look to the book of Petros, yeah, there are some sort of ligaments that are stabilizing the urethra, and if you use a textile as reenforcement of this weak structure to treat this patient, yeah, it should be considered as a replacement of a ligament. And even from the form, you're dealing now not with a flat mesh area, but with a 1 centimeter width. So that is the difference. 20 to 1 centimeter.
QUESTIONS BY MR. THOMAS:
Q. So it's your testimony that the forces that are applied to the mesh by the body are uniaxial in nature all the time?
MR. ANDERSON: Objection. Asked and answered.
THE WITNESS: No, that is not correct, not all time.
It is a justified assumption that it gives important information to have this testing in a uniaxial

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direction. It helps us to define -- to define the requirements to a textile which is intended to replace a ligament in this setting and then you have to define the range not to get the risk of being over engineered. And the Mühl testing just covers one -- some range within this.

QUESTIONS BY MR. THOMAS:

Q. For mesh that is implanted for the treatment of stress urinary incontinence, if a force is applied to the mesh, both ends of the mesh have the flexibility to move, don't they, with the tissue?

MR. ANDERSON: Objection to form.

THE WITNESS: Yes. They have the -- yeah.

QUESTIONS BY MR. THOMAS:

Q. Okay. In the test method that you and Dr. Mühl devised for the measure of the uniaxial loading, when you test the force to measure the effective porosity, one end of the mesh can't move, correct?

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A. Yes. And this leads to the question what period of implantation of mesh you want to get this information for.

If you're looking for the situation where the surgeon applies this material, he has to have it in his hands. So he fixed one immediately and that is a situation that is probably more closer to the testing.

Of course, there is another situation after three months, after one year when you have all of this tissue integration there and so.

Q. Let's go to page 59 of your report, please.

Right in the middle of the page you're talking about, "The danger of heavy-weight, small pore hernia mesh and its impact on tissue reaction when using the hernia mesh Prolene® for your gynecological slings," correct?

A. Yes.

Q. You say, "It is my opinion to a reasonable degree of medical and scientific certainty that there is no rational reason why the TVT® needs the stability and the amount of material of the Prolene® hernia mesh which can only be regarded as over engineered for this purpose."

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Now, we've talked about that at length, haven't we?

A. Yes.

Q. You continue in your opinion, you say, "It should be mentioned that in the field of abdominal wall hernia repair, the use of large pore, light-weight meshes has become a standard recommended by guidelines and meta-analysis."

Why is it important to you that in the field of abdominal wall hernia repair the use of large pore, light-weight meshes has become a standard recommended by guidelines and meta-analysis?

A. Just to confirm that the fact that large pore textile constructions are widely accepted in the field of abdominal wall hernia surgery with all the history, and this is not only a fact that is indicated by some preclinical animal experiments, but it is widely accepted in the world of surgery that, yeah.

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Q. When you talk about a standard recommended by guidelines, to what are you referring there?

A. There are the European Hernia Society that has guidelines for the treatment of groin hernia, and they said that it is advantages to use a large pore, light-weight meshes. There is the International Endoscopic Hernia Society that has recently published guidelines for the treatment of endoscopic hernia repair and now for the treatment of laparoscopic incisional hernia repair under the guidance of Bittner, Professor Bittner, and they have a chapter, "Impact and Selection of Mesh Material," and there it is clearly expressed that large pore constructions have advantages and should be -- should be used and in these guidelines, you will find the references to the meta-analysis that has been published some in Hernia.

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I know that there are some meta-analysis coming to the result -- nonsignificant result -- difference, but more or less taking these meta-analysis and these guidelines. It is well-accepted in the society or in the field of hernia surgeon to use material reduced large pore meshes. It's no doubt about it. No -- yeah.

Q. No doubt about it based upon the standards you just identified --

A. Not based upon, but this -- these guidelines are reflecting the literature, the opinion of experts, there are different levels of recommendations. So it's not because of the guidelines, but the guidelines indicate that this acceptance of the surgeons.

Q. The meta-analysis studies the data, correct, and collects the data and draws conclusions from the existing studies?

A. Yes.

Q. And the guidelines to which you refer are the guidelines of the professional organizations who have experience in hernia

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surgery who are familiar with the literature and they publish as a professional organization their opinion as to the proper mesh to use in the hernia application?

A. I don't know whether I got the point. These are not professional organizations. These are organizations by surgeons. They have according to the protocol of the oxford community how to make guidelines. You have to make a reading of the literature. You have to classify the literature according to the level of evidence. You have to add the expert comments on it. You have to pass it several times around so that everyone can give his comment and finally you have some statements, what are the facts and then you have finally some recommendations.

And this is not a commercial thing that is our -- this is the enthusiasts trying to define the best therapy.

MR. THOMAS: Let's take a break for lunch.

MR. ANDERSON: Sounds good.

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(Off the record at 12:27 p.m.)

(Klinge Exhibit 22 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, I hand you a document that's been marked as Deposition Exhibit Number 22.

Deposition Exhibit Number 22 is a section from a book called "Hernia Repair Sequela," written by Volker Schumpelick and Robert J. Fitzgibbons.

Is that Professor Schumpelick the same person that is your superior at your office at the university?

A. That was?

Q. Is that the same Schumpelick that you worked for at the university?

A. Yes. Yes.

Q. And who is Robert Fitzgibbons?

A. He is an American surgeon who is a co-editor for this work and the cochairman for this conference.

Both are editors of the Hernia Journal still additionally to Marc Miserez

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from Leuven. These three from it.

Q. And it says it's in collaboration with Joachim Conze; is that right?

A. Yes.

Q. And that's the same Dr. Conze that you worked with at the Aachen group?

A. Yes.

Q. I'm sure you're familiar with this chapter, aren't you?

A. Yes.

Q. If you turn to -- it's 2010.

The third page reads, "Alloplastic implants for the treatment of stress urinary incontinence and pelvic organ prolapse," shows you as a coauthor with -- and who are those people?

A. This was B. Schuessler, it's Professor Schuessler from Luzern. He's the head of the gynecological department there, and he's giving this presentation at the St. Moritz meeting. And T. Kavvadias is a coworker of this department who prepared the manuscript. It was a summarize -- or it's --

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the manuscript that should be printed and the content of the presentation of Professor Schuessler.

Q. Did you have any responsibility for the presentation of Professor Schuessler?

A. My relationship with Professor Schuessler is that we share a lot of ideas, a lot of knowledge. We prepare together some publications and, therefore, some of his ideas are reflecting our experiences in this -- in this meaning, yeah, I'm responsible for some of the contents he presented there.

Q. Okay. What responsibility did you have for the preparation of this chapter in this book?

A. I was asked when they prepared this manuscript as the basic content of the presentation of Professor Schuessler. They asked me to revise this manuscript because some of these aspects are mainly based on our work and our experience and, therefore, I was asked to give my comments and corrections to this manuscript. So I'm a coworker there.

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Q. If you turn to page 440 of Exhibit 22, that's a category that says, "Meshes in Stress Urinary Incontinence."

Do you see that?

A. Yes.

Q. Second paragraph says, "At present, the gold standard in SUI surgery is the suburethral sling, using tension-free vaginal tape, (TVT®) or the transobturator tape, (TOT) technique."

Do you agree with that statement?

A. I wouldn't have chosen it. We had similar discussion in our field of surgery is there any gold standard, what is a gold standard. I made several presentations about this. Today I wouldn't select the word "gold standard," but it is not -- I don't see that it is a serious mistake to use it in this context of this article.

Q. Okay. You see in the last paragraph of that column, right in the middle they're talking about "A prospective randomized control trial by Mechia so that

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vaginal erosion of Amid type III mesh used for intravaginal sling plasty was as high as 9 percent in a two-year follow-up, which is significantly higher compared to zero percent using the classical TVT®, type 1 macroporous monofilament polypropylene mesh in the same trial."

And that's the Johnson & Johnson mesh, Ethicon?

A. I guess I have seen the original publication to this, but it would be misleading to not to mention the first sentence, "Less erosion rates depend on the selection of the material" and, therefore, this study and this article confirms the finding of this study that there is an impact of the material on the clinical outcome and whether it's 9 or zero percent, 1, the power of this study is not sufficient.

Q. You stand by the language in this exhibit, don't you?

MR. ANDERSON: Objection.

THE WITNESS: I don't see any big conflicts of interest or big

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mistakes there.

QUESTIONS BY MR. THOMAS:

Q. What do you understand "gold standard" to mean?

A. Gold standard is a difficult word. I wouldn't use in the moment to define anything.

(Klinge Exhibit 23 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Let me show you what I've marked as Deposition Exhibit Number 23.

Deposition Exhibit Number 23 is another study that you've been associated with.

You recognize this as the Klink study we talked about yesterday?

A. Uh-huh.

MR. ANDERSON: Yes?

THE WITNESS: Yes.

MR. ANDERSON: Thank you.

QUESTIONS BY MR. THOMAS:

Q. And this is a comparison of long-term biocompatibility of PVDF and

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polypropylene meshes, correct?
A. Yes.
Q. What role did you have in this study?
A. My role in this study was mainly to have a look to the data and to work on the manuscript with the interpretation and the presentation of this data.
Q. And all of the authors on this study are associated with the universities?
A. That's true.
Q. And what specialty or discipline does C.D. Klink have?
A. He's a journal -- he's a surgeon. He's a general surgeon.
Q. And Dr. Junge, what discipline or expertise does Dr. Junge have?
A. The expertise or the medical profession, he's a surgeon as well. His expertise is that he has been working since 1996, '7, I guess, in our group. We made a lot of different investigations there so he has a -- he's very familiar with all of these work what we have done.

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Q. And M. Binnebösel, who is that?
A. He's a surgical resident who later on came and mainly he worked in this field in the past five, six years.
Q. Who is the next person?
A. Dr. Alizai, he's a young resident. He has not finished his surgical training education and he's just at the beginning of his career.
Q. And how about the next person?
A. Dr. Otto, he is a surgeon. I think he has been -- he's finished his education as a surgeon. He's working scientifically for some years meanwhile and in our group, if you want to say, so he mainly is busy to investigate this visible mesh structures.
Q. And Dr. Neumann?
A. Professor Neumann is the head of the department.
Q. The department of surgery?
A. Of surgery.
Q. Took Professor Schumpelick's position?

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A. Yes.
Q. And what was the goal of the study?
A. The goal of the study was to see long-term differences between PVDF and polypropylene meshes.
Q. And the materials that you used for this study were supplied by FEG, correct?
A. Please let me have a look.
Q. It's on the second page under "Mesh Materials."
A. Yes.
Q. Do you know whether FEG provided those materials or you were required to purchase them?
A. I don't know.
Q. All right. And the mesh materials used in this study -- strike that.
One of the things that you also did in this study was to take scanning electron microscope images of the explant, correct?
A. Yes.
Q. And on page 294 of Exhibit 23,

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down under "Results," it says, "Exemplary electron microscopy of explanted samples revealed the signs of surface cracking of the polypropylene samples which were not detectable on the PVDF samples." And then on the right, there are images of what was found in the study, correct?
A. Yes.
Q. Dr. Klinge, have you discussed with FEG the fact that the polypropylene that they use in their mesh implants displays surface cracks such as are depicted in photograph 9 or page 294?
A. We discussed these results, yes.
Q. Did you discuss with FEG any risks that you saw to patients who received the mesh due to the surface cracking that appears in paragraph -- or picture A on page 294?
A. Not specifically.
Q. Have you discussed with FEG at any time any risks of danger to their patients because of surface cracking such as

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that depicted in picture A on page 294 of Exhibit 23?
A. We -- since we started to think of PVDF in 1998, we were working to figure out the advantages of PVDF. And, therefore, the study just to us was a confirmation of the findings from others and demonstrates the advantage of PVDF. I didn't -- yeah, that's it.
Q. Okay. FEG uses polypropylene in some of its implants, correct?
A. Yes.
Q. And you've been aware that FEG uses polypropylene in some of its implants for some time?
A. Yes.
Q. You've been aware that -- you understand from conversations with Clavé and Klosterhalfen and others, that there have been reports that surface of some polypropylene meshes show cracks?
A. Yes.
Q. Have you ever discussed with FEG any risks to their patients because of

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these observations of surface cracks?
A. It is -- I always make it clear and Bernd Klosterhalfen made it clear since 20 years that using polypropylene in comparison to PVDF has an increased risk, yes.
Q. Did you tell specifically FEG that the surface cracking in these photos presented a risk to their patients that received their mesh?
A. They know this, yes.
Q. My question is: Did you tell them that?
A. Yes, we -- yeah.
Q. And what did you tell them about the risk?
A. That there is a potential risk of this surface cracking that sometime it may be related to some increased inflammatory reaction, more infections. So we always told what is the consequence of a surface cracking. That is an increase of surface with all of the consequences and, therefore, this is an increased risk if you have a

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material that shows this.
Q. And who did you tell FEG about this increased risk?
MR. ANDERSON: Who did you tell -- who did you tell FEG?
QUESTIONS BY MR. THOMAS:
Q. Who did you tell at FEG about this increased risk from what you observed in this photograph on paragraph A on page 294?
A. To everyone. I'm sure everyone. All of the -- all of the people that are involved in this mesh design, that was it and I've discussed it with them.
Q. Dr. Obolensky?
A. Yes.
Q. Mr. Mullen?
A. Yes.
Q. Do you know whether FEG has ever taken any steps to warn the surgeons that use their products of any risk from degradation -- strike that.
Do you know whether FEG has ever taken any steps to warn the doctors who use their mesh about any risks from the

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surface cracking that's observed in paragraph A?
A. I'm not familiar. I'm not familiar with the legal things, what has to do something with warning here and informing.
My relationship to the FEG is that we together we're in favor of the PVDF and that's it. And they tried together with me to make more and more devices only of pure PVDF.
Q. You don't want to be associated with a product that creates a risk of harm to patients they don't know about, do you?
MR. ANDERSON: Objection to form.
THE WITNESS: I didn't understand this question.
QUESTIONS BY MR. THOMAS:
Q. You don't want to be associated with a product that creates a risk of harm to patients they don't know about, do you?
MR. ANDERSON: Objection to form.
THE WITNESS: You have to -- in

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Germany, you have to inform patients about risks with a rate of 1 to 10,000, so in this area.

In the moment, we have the information of a surface cracking since some years, five, six, seven years, and before the time we thought it was stable. We believed what they have seen there. So this is a recent finding and still today there are a lot of -- there are some people from the manufacturers and saying that is just an artifact. It's not a real complication. We know there are some potential risks by the increase of surface by this, but I cannot figure out what is an exact ratio. I even don't know what happens after 30 years, after 40 years.

Our experience up to now is that within the first two years, three years, there is no report about a ruptured degradated mesh material leading to a recurrence or to a

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clinical consequence.

We have no doubts that it happens, meanwhile the consequences has to be carefully surveyed during the next time.

QUESTIONS BY MR. THOMAS:

Q. You used the rate of one in 10,000. Do you have enough information available to you to determine whether the risk to a patient who receives a polypropylene mesh from FEG creates a risk greater than one in 10,000 that they will suffer adverse consequences because of that mesh?

A. My current opinion to this point is that at the moment we don't have sufficient data to quantify exactly the consequence of this finding to the clinical outcome. We don't have any doubt, there is no doubt that it happens, that you have this degradation and there is no doubt that in principle, surface enhancement leads to some complications. But I will not -- or to my opinion, to my knowledge, it is not like this

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that the risk is so high that you have to stop any use of polypropylene in the moment in all devices for all purposes. And that is what I expressed clearly at my presentations as well. It is a concern and to my opinion, there is no doubt that this happens, but it is not enough to forbid the use of polypropylene in medicine in the moment. But maybe it happen. It changes.

Q. What should FEG do about this knowledge and its surgeons and its patients that receive this mesh?

A. I don't have any specific information what they are doing as a consequence of this. To my knowledge, the way was to use only PVDF.

Q. Okay. But is it fair to understand that based upon your knowledge of the information available to you at this time, you're unable to determine the extent to which there is any clinical significance to any surface cracking that may be on this polypropylene mesh manufactured by FEG; is that fair?

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MR. ANDERSON: Objection to form.

THE WITNESS: As I told before, I have no doubts that surface cracking and enhancement of surface leads to a higher risk for complications. That is a clear relationship, causal relationship, that is proven by all our experience and all of this work.

I cannot give you a figure what does this mean to have these materials, but this should be a starting point. If you decide -- and that is my consequence, if you decide to sell polypropylene further on in your devices, you should study it very, very carefully because this, of course, is not -- a nonlinear process. It happens -- it may happen that 20, 30 years after implantation in young patients that you may experience things you don't want to see there.

So it has to be studied there.

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QUESTIONS BY MR. THOMAS:
Q. Do you have any ideas as to what you would expect to see?
A. In the worst case for the patient, it can be a malignant transformation because you have 30 years of chronic inflammation. We know this from medicine in general. Chronic inflammation over 30 years may cause some malignant transformation, and, this was, of course, the severest complications for the patients, yeah.
Q. Polypropylene sutures have been used now for over 50 years, haven't they?
A. Yes.
Q. Are you aware of any reports in the literature about clinical issues associated with alleged surface cracking in polypropylene sutures?
A. When we're looking to the literature, the number of scientific investigations of tissue response to foreign body materials is very, very limited and mainly for the meshes with the huge amount of sutures, it would be a better material to be

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investigated these effects with meshes. It mainly started in 1994. So you don't have a knowledge of 50 years of extensive research in this field.
When you -- if you would asked me five years before whether do you know some cancer case in relationship to textiles, I would say, no, I don't know any report, but meanwhile it changed. Meanwhile we know some.
I don't want to say that we have to expect it in certain number of patients, but it is a concern, yes.
Q. Are you aware of any reports in the literature about clinical issues associated with alleged surface cracking in polypropylene sutures?
A. Polypropylene suture surface cracking, there has been reports. I guess La Roche was an investigation of polypropylene sutures in the eyes showing this cracking or degradation of this material. So there is some literature showing that indicating that you have this degradation.

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Q. My question is not whether you show the surface cracking. My question is whether there are clinical manifestations resulting from the alleged surface cracking?
A. I don't know any study that was able to differentiate whether it was a surface cracking, whether it was a surface of the material, whether it was the functional biocompatibility of the device, therefore.
Q. Last year when you testified, you testified that polypropylene mesh appropriately designed could be used in a mesh.
Do you recall that?
A. Yes.
MR. ANDERSON: Objection. Mischaracterizes his testimony.
Go ahead.
QUESTIONS BY MR. THOMAS:
Q. Do you still believe that?
Has your opinion changed?
A. No. Can you, please, because it depends on -- can you please repeat?
Q. Is polypropylene fiber still an

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appropriate material to be used in a mesh?
A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes.
Q. As --
MR. ANDERSON: Let him finish.
MR. THOMAS: I thought he was, I'm sorry.
MR. ANDERSON: He's still counting on his fingers.
THE WITNESS: When I would prefer the best material, I wouldn't choose polypropylene.
QUESTIONS BY MR. THOMAS:
Q. Is PVDF more expensive than polypropylene?
A. It's definitely more expensive, and it's more difficult to handle.
Q. And how much more expensive is it than polypropylene?
A. I don't know.
Q. When you say it's more difficult to handle, what do you mean?
A. What I was told by the textile

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engineers since over the past 15 years, you need a specific knowledge of how to make PVDF fibers because you need higher temperature to do so, you need specific equipment, you need other -- other spinning equipment to do so. Yeah. The advantage is that you can use a pure material.

Q. Dr. Klinge when a mesh is implanted, what bodily fluids surround the mesh.

A. Immediately when you place it there, depending on the skill of the surgeon, some blood. Usually some blood.

Q. Do proteins ultimately surround the mesh?

A. Yes, of course. There are some body liquids from the extra cellular liquids and they contain thousands, hundred thousands of proteins and due to the trauma, to the stress by the implant, you have a accumulation of liquid in this area. If you look very carefully to this area, you always find some accumulation of liquid around a textile implant.

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Q. Is it true that proteins surround the mesh fibers?

A. Our current thought is that the liquid containing the proteins, they are around the mesh fibers. The proteins themselves are too small. They just adhere to the surface, but they are not able to coat the entire filament to my --

Q. Okay. Do you know of any impact or effect that these fluids have on the characteristics of the mesh?

MR. ANDERSON: Are you talking polypropylene?

MR. THOMAS: Yes, polypropylene. Thank you.

THE WITNESS: It is necessary to think or to specify which characteristic of the mesh.

QUESTIONS BY MR. THOMAS:

Q. Have you ever heard of a term "plasticizer"?

A. Yes, but not in the context with meshes and proteins.

Q. That the bodily fluids as it

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gets to the mesh will make the mesh softer and more pliable?

A. I never realized this in the context with the -- with polypropylene or with meshes.

We used the pre-coating with vascular grafts. They were preclotted with some substances to change the appearance, but for textiles meshes made of polypropylene with a fiber of -- in a diameter of 120 microns, I cannot believe that any protein can change significantly the properties of this.

Q. Have you ever studied the extent to which bodily fluids soften meshes and make them more pliable?

A. No.

Q. When a mesh is explanted, the bodily fluids and proteins remain on the mesh, correct?

MR. ANDERSON: Objection.

THE WITNESS: When you explant a mesh, you usually have a block and you have a lot of scar tissue and

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somewhere in between there are these fibers. There is some liquids, some cells there, yeah.

QUESTIONS BY MR. THOMAS:

Q. And once you take the explant out, you place it into formalin?

A. Yes. Either you want to make some specific analysis. If you want to make an electron microscopy, you need some other solution for fixation, or if you want to make some genetic analysis, you have to freeze it down later on making some other -- so these are the three options you have usually.

Q. Okay. So you can freeze it, you can use formalin or --

A. Yeah.

Q. -- there's some other preparation you use for electron microscopy?

A. Yes.

Q. Tell me what that is.

A. For example, glutaraldehyde.

Q. I'm sorry?

A. Glutaraldehyde.

Q. I don't have any idea what you

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just said.
MR. ANDERSON: Glutaraldehyde. Or glutaraldehyde.
QUESTIONS BY MR. THOMAS:
Q. Okay. Under what circumstances have you used --
MR. ANDERSON: Glutaraldehyde.
QUESTIONS BY MR. THOMAS:
Q. -- glutaraldehyde in the preparation of samples for scanning electron microscopy?
A. There has been some time where we tried in some research projects to do some electron microscopy and, therefore, we had to make this specific fixation where we wanted to look to the collagen fibers. Collagen 3 has very small fibers. So when we were bound to make this fixation and we were asked to make this fixation with glutaraldehyde.
Q. Why did you use glutaraldehyde as opposed to formalin or formaldehyde, what was the reason?
A. Because we received a protocol from the guys making the electron microscopy

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and that we should use this. I'm not an expert to say the different possibilities to make a preparation for some investigation. I just told you what my experience was that we have some different options to make it.
Q. Okay. And how many occasions have you prepared slides for scanning electron microscopy where you've used glutaraldehyde?
A. How many slides for electron microscopy?
Q. Yes.
A. I don't recall. Most often I think it was to analyze the collagen, the quality of collagens. There we had -- over some years, we had projects where we made electron microscopy to look to the protein -- to the collagens.
Q. Have you prepared any samples for scanning electron microscopy in the last three years using glutaraldehyde?
A. Not that I recall.
Q. Have you prepared any samples using glutaraldehyde for scanning electron

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microscopy where you analyze the extent to which there were --
A. Degradation?
Q. -- surface cracking found on polypropylene?
A. Not that I recall.
Q. Doctor, on pages 40 to 42 of your report, you have three images that come from the report of Dr. Jordi; is that correct?
A. Yes.
Q. Did you select the images that were to be included in your report?
MR. ANDERSON: Objection as to whether or not there's work product and who selected what images.
QUESTIONS BY MR. THOMAS:
Q. Well, then I'll ask it this way.
Are Figures 13, 14 and 15 of any particular significance to you in your opinions other than just a representation of what was seen in images from Dr. Jordi?
A. I don't see any significant

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differences to many others so --
Q. Do Figures 13, 14 and 15, to your knowledge, have any relationship to Carolyn Lewis?
A. Yes. I know --
Q. I didn't see it in your report. That's why I'm asking.
A. I remember I received a lot of images from other devices, but from this device specifically as well. I guess it is from this case.
Q. How do you know that? You say I guess.
A. I have to be -- look careful every sentence there whether we have already written it here. Otherwise, if it's not written here, I have to check the files --
Q. Okay.
A. -- with the images there.
Q. I did not find it in your report where you identified these --
A. Sorry.
Q. -- images as being associated with a particular person. That's why I asked

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the question.
MR. ANDERSON: No, but he reviewed Jordi's report.
MR. THOMAS: I understand that. And Jordi has 22 mesh explants, too. I don't know which ones he picked.
MR. ANDERSON: Yeah, they're all identified by identifying number in Jordi's report. So if you want us to go get Jordi's report out and look through and identify which ones are Ms. Lewis, we can certainly take the time to do that. Or I can tell you which one it is or however you want to do it.
MR. THOMAS: I was going to ask -- I do want to see the report he has because the report he has is dated a different date than the report that you produced. The report that's identified in his report is dated October the 12th, 2013.
So do you have that with you, the one that he reviewed here?

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MR. ANDERSON: No, but it would be the exact same report as Jordi did.
MR. THOMAS: I don't -- it's 19 days before his deposition. You remember we had two marked there with different dates. I never did figure out --
MR. ANDERSON: Because we reprinted off the first page, and when we reprinted off the first page for you, we printed it as the same day as the depo.
QUESTIONS BY MR. THOMAS:
Q. As you sit here today, Doctor, do you know whether the Figures 13, 14 and 15 are from mesh explanted from Carolyn Lewis?
A. I'm not sure whether this is precisely from her, but they all look quite similar.
Q. Okay. You've told me before that you're not a chemist or an analytical chemist.
Have you studied the extent to which -- strike that.

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Have you studied how polypropylene degrades?
MR. ANDERSON: Objection. It was asked yesterday because you wanted to get into expert opinions yesterday. So we're going back over the same ground.
MR. THOMAS: Not really. I just didn't remember I asked the question.
MR. ANDERSON: You asked a lot of questions on degradation yesterday.
MR. THOMAS: Okay.
MR. ANDERSON: Because you asked to go ahead and start asking expert questions yesterday.
MR. THOMAS: Can we keep going so we can get out of here?
QUESTIONS BY MR. THOMAS:
Q. Can you answer the question?
MR. ANDERSON: Have you studied how polypropylene degrades? That's his question.
THE WITNESS: We have studying

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in the meaning that looking to the data, yes. Doing own studies, experimental studies looking to the chemistry, what happens there, no.
QUESTIONS BY MR. THOMAS:
Q. Do you defer to Dr. Jordi for that type of analysis?
A. Yes. Definitely.
Q. Doctor, let's go to page 76 of your report, please. Page 76 of your report deals with the heading "Alternative Design."
Is it your opinion that ULTRAPRO™ is an appropriate alternative design for the treatment of stress urinary incontinence in women?
A. No.
Q. Why?
A. Because the structural stability of ULTRAPRO™ is not sufficient to withstand -- or to preserve the big pores under -- under these conditions of biomechanics as it is required for the use as a sling.
Q. Is there any mesh design

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currently marketed by Ethicon that is an appropriate alternative design for the treatment of stress urinary incontinence?

A. I'm not aware of all products from Ethicon that are available in the moment. In this context, I cannot say whether there is already some device that I can consider sufficiently to be sufficient. It should have -- it has to be tested all these.

Q. And when you mean it has to be tested, what do you mean?

A. To find the optimum structure, the optimum -- the development -- for the development of the optimum structure, you need some studies to define this.

Q. Tell me what studies you need.

A. More or less you need studies to every point of concern that was mentioned in this report and this -- these studies to every point mentioned in this report should -- has to include a lot of preclinical studies in appropriate animal models, in appropriate functional testing, in

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appropriate textile characteristic and then you may get a good impression which design of this -- of your device you want to have is -- has the lowest risk.

Q. So first thing you mentioned preclinical studies.

Is that animal testing?

A. It can be in vitro testing. It can be animal testing.

Q. Do you need both?

A. Yes.

Q. And the in vitro testing is what?

A. In vitro testing is maybe it's the counting of particle loss after manufacturing. It can be the behavior in liquids, the degradation, the combination of these materials with some cells, what happens there, what is the overgrowth. A lot of questions can be addressed in this field.

Q. Okay. And do you need to do the in vitro and animal testing before you do the function testing?

A. Everything has to be in

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parallel. If you want to have a good schedule for how to do so, a good example of -- a good realization of this principle is what we have done with the VYPRO or the principles that we defined at that time, all of these studies, the 100 publications, all of this together gives a good impression or helps you to understand, to find a good device.

Q. And you began with the design of VYPRO in 1994?

A. 1994.

As I told you, December of 1993.

Q. And when was VYPRO launched?

A. 1998.

Q. Is it your opinion today that PVDF is the only appropriate polymer to be used in mesh for implantation in the treatment of stress urinary incontinence?

A. No, but, to my knowledge, it's the best we have.

Q. What other polymers are appropriate for use in a mesh for

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implantation in the treatment of stress urinary incontinence?

A. I cannot answer. This is a very general question. There are a lot of polymers, experimental. We're working on polymers and other polymers so there are a lot of other -- maybe a lot of other alternatives. There are some literature providing new materials but in the moment from my -- to my knowledge, PVDF has the best results.

Q. Okay.

A. But I cannot give you a complete list of all alternative -- possible alternatives.

Q. Can you give me a list of three possible alternatives?

A. I cannot give you a list of one alternative that is better than PVDF.

Q. And I know that.

What I asked you is there --

A. There are some polyimides, polyulitars. These are classes where you can try to look to see alternatives.

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Q. Is it your opinion today that polypropylene is not an appropriate mesh for implantation for the treatment of stress urinary incontinence?
A. I think some minutes ago I already said that the word "appropriate" is -- makes it impossible for me to say yes.
Q. Is it your opinion to a reasonable degree of scientific and medical certainty that the use of polypropylene in meshes for the treatment of stress urinary incontinence is unreasonably dangerous?
A. Unreasonable dangerous? Has to be seen in regard to the specific situation of the benefits and risks. If you use this implant of polypropylene in an 80-year-old patient, I will not expect that you will experience any problem just because of degradation within the next one year. So it --
Q. Do you have a --
A. I cannot give a general statement to this.
Q. Okay. Do you have an opinion

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to a reasonable degree of scientific and medical certainty whether it's appropriate to use polypropylene mesh in hernia repair?
A. The same objection as before, the term "appropriate."
Q. Do you have an opinion --
A. Makes it difficult or impossible for me.
Q. Do you have an opinion to a reasonable degree of scientific and medical certainty as to whether the use of polypropylene in hernia repair is unreasonably dangerous?
A. The -- my present opinion is that it is not so dangerous that it should be forbidden in today to have -- to use it and, therefore, I'm convinced that it is tolerable or acceptable to use polypropylene in medicine.
Q. Okay.
A. But if I may, it depends on the structure.
Q. Right.
A. So it's not a general free

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comment on polypropylene in general.
Q. I understand that.
And, Doctor, you have to start somewhere and choosing the textile is a pretty fundamental issue for any mesh that you might use, you agree with that?
MR. ANDERSON: You mean the polymer?
MR. THOMAS: Yeah, that's what I meant.
QUESTIONS BY MR. THOMAS:
Q. Doctor, you have to start somewhere and choosing the appropriate polymer is an important first step in the design of any mesh, would you agree with that?
A. Yeah. I would agree that this is a first step because then it leads you to further decisions.
Q. And even a PVDF polymer can be designed in a way that's unreasonably dangerous, do you agree?
A. Definitely, yeah.
Q. And so as I understand your

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position for use in medicine today, either PVDF or polypropylene are appropriate -- or excuse me, are not unreasonably dangerous if designed correctly?
A. Again, there is this inappropriate. It depends on what you're looking. You can create some acceptable textile structures of both, of polypropylene and PVDF. You will find some different risks if you compare these two.
Q. Doctor, what is Exhibit A to your report? That's it right there. Those images.
A. These images?
MR. ANDERSON: That's Exhibit A?
MR. THOMAS: I think.
MR. ANDERSON: A was his CV.
MR. THOMAS: I am sorry, then Exhibit C. I apologize.
QUESTIONS BY MR. THOMAS:
Q. What is Exhibit C to your -- let me start over again so I get a good question and you give me a good answer.

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Doctor, what is Exhibit C to Exhibit 11?
A. Exhibit C is a collection of images I made from histological sections I received, and I received HE stainings and stainings with S100.
Q. Okay. Now, did you create the images that are in Exhibit C?
A. Yes, myself.
Q. And what did you receive -- strike that.
I take it you received certain materials from Mr. Anderson that allowed you to make these images, correct?
A. I received complete stainings in a box, each explant were prepared with the three stainings, three sections.
Q. So by the time you received them, the slides had already been stained?
A. Yes.
Q. And what stainings were done?
A. HE, this is this one with the red color, and there is an additional staining with a specific antibody S100 that

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marks nerves or nerval structures. This is a link to a brown color so in these you have this brown color where the S100 is positive.
Q. Okay. Is the HE two different stains or just one?
A. No, it's two.
Q. Okay.
A. Two.
Q. So you have one -- two --
A. No, it is two colors that are brought to one section. So it's a counter staining.
Q. You told me, I thought, that you had three slides?
MR. ANDERSON: Three of each.
THE WITNESS: Three of each.
Three HE from patient or from case one, and three S100 from case one.
QUESTIONS BY MR. THOMAS:
Q. I see.
So you have six slides for each patient?
A. Yes.
Q. So you have 66 -- no, you have

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132 slides?
A. You're right. I'm not a mathematical expert. It's a big number.
Q. Do you know who prepared the slides?
A. Professor Kreutzer. I received a note that he prepared this with some numbers so that I can check whether the number of this data sheet was the same as on the slide, on the --
Q. Did you have any interaction with Dr. Kreutzer about how to prepare these slides?
A. Not directly.
Q. Did you provide information to anybody to give to Dr. Kreutzer about how to prepare these slides?
MR. ANDERSON: Other than conversations with me?
QUESTIONS BY MR. THOMAS:
Q. Let me ask it this way.
Doctor, do you know how Dr. Kreutzer prepared these slides?
MR. ANDERSON: Objection to

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form.
Go ahead.
THE WITNESS: I don't know in detail, but this staining HE is a normal procedure for every pathological department and the doing of S100 staining is a -- it's a standard procedure. Maybe I can use the word "standard" in this context. It is published in all of the reports where we presented these data. It is no specific knowledge to do these two.
QUESTIONS BY MR. THOMAS:
Q. What's Dr. Kreutzer's training, if you know? I've forgotten.
A. He's pathologist.
Q. That's what I thought.
And he's in Connecticut.
Have you ever met him?
A. No.
Q. Spoken to him?
A. No.
Q. Did you have any communication with Dr. Kreutzer at all about the slides

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that he presented to you?
A. No.
Q. Have you ever seen any written analysis by Dr. Kreutzer of the images that are attached as Exhibit C to your report?
A. No.
Q. Tell me again what an HE slide is.
A. HE slide is a staining of cells and of extra cellular matrix, mainly of collagen. So you have a blue color for the nucleus of the cells to identify the cells and you have a red staining mainly for the collagen and, yeah.
Q. Let's go to the very first slide that you have, very first image that you have on Exhibit C.
And down in the lower right there is a scale of 500 microns, correct?
A. Yes.
Q. And what's the magnification of this, do you know?
A. I don't know in this, but when I made the image there, I was asked -- I

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usually took the 40 magnification, 100, 200, 400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.
So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a look through the different things, then, of course, we will see whether it's the 400 or the 40.
Q. Well, there are different -- I see different scales throughout these photographs.
A. It's 40, 100, 200, 400 magnification.
So as I recall, these are the four different magnifications and there will be correspondingly four different scales here.
Q. Okay. What does this tell you about this first image in Exhibit C with -- lower right-hand corner it says 500 microns.

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In the middle of the first image on Exhibit C, there's a measurement of 168.53 microns.
Can you tell from looking at this image what the magnification is?
A. The magnification would be 40 or 100.
Q. Okay. Now --
A. When I saved the images, I name it so usually I get it from the name.
Q. I believe that one doesn't have any scale on it at all.
A. Yeah, sometimes I forgot it. Sorry. So 200 -- no, 500, 50, this is the highest magnification. This is 400, then this is 40. 40. 40 fold magnification.
Q. And how did you conclude that?
A. Because I've seen there one with the highest magnification and this was 400. And so in this the scale was only 50 and here we have 500 so it is one-tenth.
Q. Now, you made these images yourself from a scanning electron microscope?
A. No, from a conventional light

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microscope.
Q. And where did you have that light microscope?
A. In our lab on the third level in room 45 at -- no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.
Q. Thank you, Doctor.
The first image to Exhibit C, I believe you said the red area depicts collagen.
A. It's mainly collagen, yeah.
Q. And what does the tan area represent?
A. The tan?
Q. This area over here, I call tan.
A. Here?
Q. Yes.
What is that?
A. There is nothing. No cells there.
Q. Does that mean there's no tissue?

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A. No tissue on this.
Q. Does that mean the slide does not contain any tissue as you're looking at it?
A. Yes.
Q. Okay. Does that mean that the area marked as 168.53 is at the right extreme of the sample you're analyzing?
A. In this picture, yes.
Q. And what is the area marked as 168.53?
A. This is a fragment of the polymer fibers. When looking to the slides, the first thing I try to do is to measure the diameter of these fragments so I know that there is a -- the cutting of these fragments is not directly horizontal to the course of the fibers.
But to have a rough impression what is a diameter of the fiber that it is in the area that I expect to be there.
Q. Doctor --
A. So that is around 150 microns.
Q. Okay. Now, do you believe that

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this -- is this a mesh fiber, is that what you're saying?
A. It is consistent with the -- with the fact that the -- that this fiber has the diameter of 160. If I would have seen a polymer with only 4 microns from this, then I would have some doubts that it's the right material.
But this finding is consistent with a polypropylene fiber of a TVT®-O or TVT®.
Q. So what does this mean to you?
What's the significance of this finding on this slide which is the first slide of Exhibit 3 to your report?
A. It's consistent with the assumption that it's a TVT®-O or a TVT®. If it would have been 250 or 300 microns, then I should to rethink about it. It's just a confirmation that I really just got what was written in the table.
Q. And so you're consulting a table as you review these images; is that correct?

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A. I have the information of this table, yeah, but usually I look to the images and without any knowledge so in a blind fashion.
Q. I understand.
Did you prepare the table which is prepared as the last page of your report?
MR. ANDERSON: I prepared it in accordance with the chain of custody forms.
MR. THOMAS: Did you prepare all of it?
MR. ANDERSON: Well, I had to get his ID number and the Jordi ID number and the Steelgate specimen number and all of the information that Steelgate had in conjunction with the various other information so that I could assimilate his -- the information that he provided on his ID number, and then everything from N to R he prepared or gave the information.
So the reason for doing this was to make it A, easier to keep up

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with the chain of custody so that you could see where it went from explant to his hands. It would also be consistent with the chain of custody forms that Mr. Snell and I agreed to and so it would make it easier at this deposition for you if you wanted to look at a particular device or whatever and be able to compare them.
So that was the effort that I put forth in order to try to put the information of all of the slides in one spot for both you and I.
QUESTIONS BY MR. THOMAS:
Q. And the identifier for these slides is in the lower left-hand corner; is that correct?
A. That is the number or the coating that I found on the slide, on the stainings, yeah.
Q. Was this number already on the staining or did you have to add it to this document?
A. No. I used -- I used -- I used

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the number from the stainings from Professor Kreutzer and then I placed them or I named the images according to this number and added the sort of staining and added the magnification in the name of the slides.

Q. Did you receive all -- did you see -- is 22 slides all you received or did you receive any more than that? Excuse me, strike that.

Did you receive slides from 22 separate patients, or did you receive more than that?

A. No, 21, 22 cases, different cases.

MR. THOMAS: Can we take a break a second, please?

MR. ANDERSON: Sure.

(Off the record at 2:42 p.m.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, looking again at the first image of Exhibit C to your report, what of significance do you find in this image related to adverse reaction to mesh?

A. Just to explain I looked

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through all of these stainings there and I define some parameters which I've been looking at and these I put in this table and then I made some exemplary images of every case. It's even at this low magnification, it is just one small part of the section. The section is much bigger, and, therefore, I just want to cover the general impression of any of these findings that are on the table by these images.

So what you see here is appearance of a polymer fiber in a size that we expected. You see some fat tissue there at the lower part and you see extensive tissue here very close to this fiber. And this is indicated by the red color. This is the content of this image.

Q. Is fat tissue and collagen the same thing?

A. No. The fat tissue is this lower part by the fixation, by the staining. Essentially the fatty liquids are removed so you have almost empty spaces there and you can identify fat cells that you only have the

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cell wall around, and in these cells, the nucleus is at the bottom and you have an area in the middle where the fatty acids have been and, therefore, it is bright. You don't see significant structures in the fat tissue.

Q. Okay. So you showed me the fat tissue and the collagen and you've also shown me the polymer fiber.

What else is of significance in the first slide of Exhibit C?

MR. ANDERSON: Objection to the form of the question.

THE WITNESS: I wouldn't point out any others.

QUESTIONS BY MR. THOMAS:

Q. Okay. When you looked at the 22 different patients you said that you developed some parameters.

What does that mean?

A. The parameters I want -- in general, this -- looking at these samples I want to get a confirmation that what we have seen in all these animal slides, what we have seen in the human explants from the abdominal

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wall that this is confirmed by explants provided by Professor Kreutzer, as well and, therefore, the first is that I look to the fiber size, I try to measure it, that I really am sure that it's a monofilament -- a monofilament in a size that has to be expected there, that was the first.

The second is the bridging, whether I see pores, the room between two filaments that are filled with fat and I made a coating to get or to differentiate whether these pores are frequently seen, rarely seen, always seen or never seen.

The next was whether there was some sign of folding on shrinkage. The main structure should be -- if there is no folding and shrinkage, should be in a plain way detectable in these stainings or shouldn't be in a folded or in a wave-like position.

If I saw somewhere at the mesh that there is a doubling of the structures or there is a configuration that cannot be explained by a plain positioning, then I marked it with a yes.

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And then finally I looked at the S100 stainings, whether there are some nerves in the -- within the scar area of surrounding the mesh because in former times, there has been the discussion the big nerves are not in this area, therefore, it is impossible that the mesh interacts with some nerves and for this purpose, I just mentioned whether there are some nerves, yes or not, and in fact, you see nerves in this -- small nerves that cannot be visualized by the surgeon during the operation, but you have there some nerve structures very close to this wound.

These are the four points and every slide I analyzed to get an opinion on these four things, for every case.

Q. The parameters that you've just described, are those parameters unique to this case?

A. Yes, unique.

Q. Okay. And why did you pick those parameters?

A. Because the value of this -- of

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these explants is that they allow me to confirm that -- or to test whether what we have seen in the animal tissues, in the human tissues of the abdominal wall, whether this is true for these. I had the data from Professor Klosterhalfen from his explants and it already indicated that it is similar or comparable and now I personally have the option to test -- to have it tested at these 22 sections.

Yeah, overall, in fact, you see this extended bridging there, you see that the distance between the fibers is less than these 1,400 microns. So it is -- it underlines, again, that it is irrelevant to discuss these 1,400 because if you look to the tissues, you see this bridging with these devices.

Q. Okay. You said a number of things in your answer I want to talk about.

You mentioned you received some explants from Professor Kreutzer; is that right?

MR. ANDERSON: Objection.

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Slides.

THE WITNESS: Slides.

The data explants from Professor Klosterhalfen.

QUESTIONS BY MR. THOMAS:

Q. That's better. I thought he said explants. That's -- so the only thing you received from Dr. Kreutzer were the slides?

A. Yes.

Q. Now, the information that you received from Dr. Klosterhalfen was the data that he generated from his analysis of his explant collection, correct?

A. No, I got his data and I had the opportunity to have a look at some stainings in Düren as well.

Q. Okay.

A. So I've seen it.

Q. But just so I understand, the stainings that you looked at in Düren were stainings that Dr. Klosterhalfen had already prepared and analyzed; is that true?

A. Yes.

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Q. And reported on his findings for those stainings?

A. Yes, but in the moment, I didn't know it. He just placed these tissues to me and so, yeah.

Q. Okay.

A. I could not relate it to the databases. It was -- again, it was one way to test whether this was confirmed in these tissues with these explants what we -- what our points of concern are.

Q. What form did the information take that Professor Klosterhalfen gave to you, the data that you talked about?

Is it a chart or is it information on the -- that contains his information -- strike that.

Did Professor Klosterhalfen give to you a document that detailed his analytical findings from his explant collection?

A. I had an Excel sheet where he had some of his findings.

Q. Is this the Excel sheet we

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talked about last year, the same sort of thing that you have on your computer?
A. Similar. Similar.
Q. Is it the same document, just more explants?
A. No. No. We talked last year about only explants, full explants, of the abdominal wall.
Q. Okay.
A. Now it is in other Excel sheet for the explants from the pelvic floor.
Q. Okay. And did you analyze the data provided to you by Professor Klosterhalfen to understand the complications which occur from mesh implants in a pelvic floor?
A. I made an analysis of this data in regard -- or to see whether these data confirm our opinions and our experience from the abdominal call.
Q. In addition to the Excel spreadsheet that you have of Professor Klosterhalfen's findings, you also went over to Düren and looked at some slides, correct?

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A. Yes.
Q. Did you look at all of the slides that he had?
A. No.
Q. How many did you look at?
A. About 20 to 30.
Q. Why did you look at 20 to 30 slides?
A. To have it seen by my personal eyes.
Q. Okay. Have you produced to us the Excel spreadsheet with the data that you received from Professor Klosterhalfen?
A. Not that I recall.
MR. ANDERSON: You have it. It was the one that we produced to you right before Klosterhalfen's depo and that was the one that Henry also gave to you at the depo or showed you at the depo.
MR. THOMAS: That's the Klosterhalfen exhibit from the BARD litigation.
MR. ANDERSON: Correct. That

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correlates to the 473, I forget the number, pelvic floor explants in Düren that he's referencing now.
QUESTIONS BY MR. THOMAS:
Q. Okay. And you were relying on the data generated by Professor Klosterhalfen in part for your opinions that you're giving from your review of these slides; is that fair?
A. There is no -- I don't understand whether you see a relation to this. We have our experience that bridging is important and so on, and we have tested by our own explants. I took the opportunity to have it controlled in Düren. I took the opportunity to have it tested by the data sheet of his and then I took the opportunity to have it tested -- test our opinions, our experience at the 21 cases that I got from Professor Kreutzer and finally eventually I took the opportunity to check this at the last 22nd of this case.
So it is subsequently permanent confirm -- or looking for a confirmation or a

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rejection of what we know.
Q. And just so I understand, this is the collection of explants maintained by Professor Klosterhalfen in Düren that I'm not allowed to see; is that true?
MR. ANDERSON: Objection to form.
MR. THOMAS: It's true, isn't it?
QUESTIONS BY MR. THOMAS:
Q. This is the collection protected by German privacy laws that limits and prohibits me from looking at it without permission from the patient.
Do you know the answer to that?
A. I have read it, but I'm not familiar --
Q. I'm talking about whether I can see it.
A. What?
I'm not an expert what are the legal steps to go over there and to do so. I read it in the depo form.
Q. Now, when you were at the

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university, you were a surgeon and you practiced as a surgeon until 2006, correct?
A. I am a surgeon and practiced until 2006.
Q. You did not work for the Institute of Pathology?
A. No.
Q. And that was Dr. Klosterhalfen who worked in the Institute of Pathology and collaborated with you on your work?
A. Yes.
Q. Are you permitted at the hospital where you work to sign pathology reports?
A. No, I'm not permitted to do.
Q. Did you have a residency in pathology?
A. No.
Q. Did you have a fellowship in pathology?
A. No.
Q. Have you ever been an editor or reviewer of a pathology journal?
A. No.

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Q. Are you familiar with the staining technique known as neurofilament staining?
A. I've read it and I know that it exists.
Q. Have you ever used neurofilament staining?
A. Not that I recall in the recent time.
Q. What is the purpose of neurofilament staining?
A. It's another option to visualize nerval structures. More specific.
Q. More specific.
It can -- okay. Did you ask for neurofilament staining of the samples that you looked at?
A. No.
Q. Why not?
A. I didn't ask.
Q. Why not?
A. Because in our experience, we made at -- or we preferred due to the advice of Professor Klosterhalfen the S100 staining

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to get an impression whether there are some nerves or not. And we're not -- or the main focus of our research was not to specify there whether it's neurofilaments or there are so many different options to use antibodies against nerves so we selected S100.
Q. Okay. You and Dr. Klosterhalfen decided which staining method to use?
A. Mainly he decided. I think we started at the -- in the '90s and he proposed to use S100 because this was established in the Institute for Pathology and we got good images and good information from this and, therefore, it is still widely used and we are satisfied with it.
Q. Doctor, isn't it true that normal vaginal tissue contains nerve fibers?
A. Yes.
Q. And so the fact that your staining picks up nerve fibers is not remarkable by itself?
A. As I told you, the intention to

Page 565

look for these fibers has been discussions we had that someone is standing up and said, okay, it cannot be that someone -- some patient has some pain because the big nerves we took care during the operation and the big nerves are far away and that just to demonstrate to an audience that there are these tiny nerves that cannot be seen by any surgeon when he's in this field, we just made it for this purpose and, therefore, we didn't make any further analysis. Just yes, no, and as you said earlier, everyone knows that these nerves are there, but some of my colleagues they don't want to know it maybe.
Q. What do you mean, "They don't want to know it"? I don't understand.
A. They ignore this fact sometimes in discussions.
Q. They ignore the presence of nerves?
A. Of these small, tiny nerves there, yeah.
Q. I see.
(Klinge Exhibit 24 marked for

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identification.)
QUESTIONS BY MR. THOMAS:
Q. Doctor, I've handed you what's been marked as Deposition Exhibit Number 24 and ask you if that's the pathology report for Carolyn Lewis?
A. Yes.
Q. Thank you. I'm sorry, I didn't hear your answer, I apologize.
A. I didn't get the question.
MR. ANDERSON: He didn't answer. He was still looking.
QUESTIONS BY MR. THOMAS:
Q. Oh, okay.
Did the pathology report inform your opinions at all about the tissue reaction Ms. Lewis had to the mesh implant?
A. I didn't get the -- did the pathology -- no, first of all, I looked afterwards to this pathology report, and as I tried to explain, I'm looking to bridging, folding, nerve contact and this is not included here. But what they describe is the usual appearance and, unfortunately, it's a

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usual report given by pathology when they get an implant, but they never looked to the pores or the extent of the scar tissue.
So I would expect a similar report in Germany.
Q. And just to be clear, there's nothing remarkable in Exhibit 4 which is the pathology report to Ms. Lewis that the pathologist found after the explantation to suggest any remarkable tissue reaction with the mesh; is that true?
A. It is too unspecific. It just confirms that the routine pathology is not able to give a detailed description of the tissue reaction to a device.
Q. Now, are you able to detect fibroblasts as you look at these images?
A. Yes, yes, you can see them.
Q. Are you able to detect microcapillary cells?
A. Microcapillary, endothelial, yes, you can see it.
Q. What is a microcapillary cell?
A. I assume that you are thinking

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of some endothelial cells forming vessels.
Q. And what are fibroblasts?
A. Fibroblasts are cells that are used to -- mainly their task is make a deposition of collagen there. They are very -- or if you have an injury or a damage in the tissue, usually the fibroblasts are called to make an unspecific repair by forming scar tissue in this field of damage and defect. It's -- they are the cells mainly responsible for the scar tissue and has to be differentiated from more specialized cells as fat tissue, for example.
Q. And what is -- what are -- what's collagen?
A. Collagen is a protein. There are 13, 16 different collagens. Mainly we have to deal with collagen 1. That is a protein of several helixes and this is responsible for the stability of fascia and of skin. It has to be separated from collagen type 3. That is a collagen that appears usually at the early days of wound healing and later on is replaced by this

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stable collagen 1. An increased amount of collagen 3 is an indicator of an impaired wound healing and indicator for high risk for recurrent hernia.
Q. Is the presence of fibroblasts, microcapillary cells and collagen bundles inconsistent with the formation of scar plate?
A. Complete different things. They are -- they contribute to the extent of a scar.
Q. But the presence of --
MR. ANDERSON: Were you through with your answer?
THE WITNESS: What?
MR. ANDERSON: Were you through with your answer?
THE WITNESS: Yes.
QUESTIONS BY MR. THOMAS:
Q. But the presence of fibroblasts, microcapillary vessels and collagen bundles are an indication of proper tissue integration, correct?
A. You can't decide from the

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presence of these cells either whether it's a scar plate or a scar net. If you stick to these words or whether it's proper or whether it's inadequate, it's just described that there is some scar reaction there, but it gives -- it doesn't give you any hint whether it's sufficient, necessary or too much scar.

Q. Have you read the expert report of Dr. Zing?

A. Yes.

Q. Okay. And do you agree with the findings of Dr. Zing?

MR. ANDERSON: Well, objection. Which ones? It's a long report.

Which ones?

QUESTIONS BY MR. THOMAS:

Q. Just generally, do you agree with the findings of Dr. Zing?

A. I need to go to the paper otherwise.

Q. Do you have a recollection of anything in the report that you disagreed with?

MR. ANDERSON: Again,

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objection.

MR. THOMAS: I understand.

MR. ANDERSON: Without letting him see the report.

THE WITNESS: My rough recollection was that he described a lot of things that I can agree to, but my impression was that he didn't have a -- or that his experience in comparing tissue reaction to different textile structures, that this -- his experience is limited.

QUESTIONS BY MR. THOMAS:

Q. Okay.

A. And that his statements whether it is a -- about the quantity in comparison to others, that there are only very few remarks on it. But otherwise we have to go to --

Q. Okay. Let's go to page 70 of your report.

Now, are the images of page 70 of your report also contained in appendix C?

A. I'm not sure. I made a lot of

Page 572

images, but I have to look whether all of these are here or --

MR. THOMAS: Do you know, Ben? I don't want to spend my time looking through the report and I'm just curious. I'll want copies of the -- I will want copies of these if they're not the same.

MR. ANDERSON: I don't know if all of them are the same, but certainly have an agreement with Burt that we can -- that we need to swap slides. Zing's come to me, mine go to you.

MR. THOMAS: Okay. I didn't know that.

MR. ANDERSON: Yeah, you-all need to talk more.

Yeah, so you'll have the opportunity to -- or have your guy look at ours and I need your guy -- I need yours, too. We just need to get that worked out.

MR. THOMAS: You need the

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slides --

MR. ANDERSON: The slides.

MR. THOMAS: -- somebody else has. They're not mine.

MR. ANDERSON: So they can be observed by someone else that are not yours.

So I can't really answer this question.

MR. THOMAS: Okay. We'll just make a record of that fact. We're not sure that the images that appear on pages 70, 71, 72 and 73 and 74 also appear in the appendix C.

Mr. Anderson advises that there's an arrangement whereby we will exchange slides so that Dr. Zing will have an opportunity to review what Dr. Klinge's reviewed, and Dr. Klinge will have an opportunity to review what Dr. Zing reviewed; is that correct?

MR. ANDERSON: That's correct. I know without every one of these

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photos and taking up your time, without comparing all of these, I know that some of them are certainly in the back.

MR. THOMAS: And probably by definition since there are so many of them, some of them aren't.

MR. ANDERSON: I don't know if that's true.

QUESTIONS BY MR. THOMAS:

Q. So going to page 70, do you know if the images from page 70 are from Carolyn Lewis? And the reason why I ask is on the next page, you refer to her by code name on page 71 for the first time.

A. Yes. And, therefore, the first images are not from this case. These are from the first 21 cases. And then later on, one week later, I got the case BAL 13-23 and, therefore, the first images are not from her.

MR. ANDERSON: It's BAL 13-23.

QUESTIONS BY MR. THOMAS:

Q. Why didn't you say Carolyn Lewis in your report?

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MR. ANDERSON: Objection.

THE WITNESS: No specific reason for it.

QUESTIONS BY MR. THOMAS:

Q. Okay.

A. When I got all this -- all these numbers, I have no problems to use these numbers. If I take numbers of -- names here, I'm not allowed -- I'm not well-informed about possible consequences there. But when I get a slide with a code, I take the code.

Q. Dr. Klinge, so the first images that relate to Carolyn Lewis appear on page 71?

A. Yeah.

Q. Now, what are the three images that appear in the middle of page 71?

A. All these are HE stainings and should give you an impression that it's only a small part of the tissue there. It's not a big section that has been stained there. And a lot of red there, a lot of deposition of collagen and I used a polarization filter.

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It has been possible to detect polymer particles better because they start to get bright there in this.

Q. Let's stay with the three images on page 71 for right now.

As you look at the three images on page 71 --

A. Yeah.

Q. -- is there anything about those images that suggests to you that there is inadequate tissue integration -- strike that.

Looking at the images on page 71, the three right there in a row, is there anything about those three images that suggests to you that there's an inappropriate inflammatory response to the mesh?

MR. ANDERSON: Objection to the form.

Go ahead.

THE WITNESS: What you see in this is in the middle part, it's a higher magnification than you see some inflammatory infiltrate close to the

Page 577

polymer that is the typical foreign body reaction.

QUESTIONS BY MR. THOMAS:

Q. I am sorry, that's a typical foreign body reaction?

A. Yeah.

Q. Okay. Thank you.

A. Foreign body reaction.

On the right side, you see that there are some fibers, and in between, the space is completely filled by scar tissue and on the left side, you see the lowest magnification, then you see, again, that there nowhere is a huge area of fat tissue, but all is a scar tissue there.

So overall, this HE staining confirms that this mesh material completely is integrated in a scar field.

Q. Okay. We talked earlier about a scar net or a scar plate?

A. Yeah.

Q. Is it a scar net or a scar plate?

A. It is obviously a scar plate

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because a scar net would require some fatty tissue in between the filaments. And if you're measuring or looking at the distances between the filaments, the filament is 150 microns and the distance is very close together. So you can suspect that this is at the linking part and not in the middle of the pores, but if you look through the entire section, you always find images like here, not the big distances.

Q. Okay. And when you get these slides, has the mesh -- does the mesh typically fall out of the slides before you analyze them?

A. Usually, it is a very thin section there and by the knives, it take the polymer fibers out and usually they are -- they are out and you only see the cells around.

Q. Okay. So you actually when you look at the slides, you're looking at a hole as opposed to the polymer?

A. Very often, yeah.

Q. Can you tell on 71 whether

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you're looking at the polymer or the hole?

A. From these images, it is very small, but I think even if you make it bigger, that you don't see directly the polymer in this, but only the holes.

Q. Okay. The middle slide depicts a normal fiber foreign body reaction, correct?

A. A typical.

Q. A typical foreign body reaction.

Is there anything else remarkable about the middle slide?

A. No.

Q. Now, the slide on the left, you said the red, does that depict collagen?

A. Yeah. Mainly collagen and this is expressing the scar reaction there.

Q. Okay.

A. It's not the yellow color of the fat tissue, but it's the red color of collagen-rich scar. Fibrotic. Fibroconnective tissue.

Q. So I thought collagen was good.

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MR. ANDERSON: Objection.

THE WITNESS: In sweeties, it's perfect. There's some sweets made of collagen. There, it's great.

QUESTIONS BY MR. THOMAS:

Q. I thought collagen deposition between pores was a good thing.

Is that not true?

A. It depends if you have a wound from a burn, then you get an extensive scar formation, and I don't know whether you have seen these images of contractures for these patients. It is a catastrophe. So scar is defect healing, but scar is part of the physiological wound repair as well. It depends on the quality and quantity of the scar.

QUESTIONS BY MR. THOMAS:

Q. Describe for me, please, in as detail as you can, what it is about the picture on the left on page 71 that shows you that this is a scar plate?

A. There is no -- not any or there is no area where I can identify a pore that

Page 581

is filled by fat tissue. That is not filled by scar and our definition of bridging was that the pore is completely filled by scar tissue.

Q. When you say "your definition," that definition accepted generally in the field of pathology?

A. That is the definition that we published since years what I -- what is accepted by the documents from Ethicon I saw, I never realized that there was any objection to this.

Q. My question is: Do you know that the definition that you used is acceptable in the field of pathology?

MR. ANDERSON: Objection.

THE WITNESS: I don't know what is your feeling, what does it mean acceptance in the field of pathology, by whom, in what specific situation?

QUESTIONS BY MR. THOMAS:

Q. Okay. Let's go to the same page on the right side, I would like for you to describe for me, please, what is

Page 582

remarkable about the image on the right side of the three section on page 71?

A. This is a section where you see in the middle the two almost circular holes where it is likely that there -- a polymer fiber has been there. You see on the left side of this image that it's a little bit not circular because you have a diagonal cutting in this area.

On the right-hand side, you may have the impression that there may have been some of the polymer fibers, but it's not clear whether it's a destruction of the tissue there by the cutting process, but, however, all of the tissue in between the fibers it is scar.

Q. Next page, page 72 at the top, there are three images there and the heading says, "Some areas of the polymer showed considerable M homogeneity of the crystal structure that can hint to a present change of the crystal structure."

What does that mean?

A. As I told you, we have -- we're

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frequently using this polarization filter because this allows us to differentiate between collagen 1 and collagen 3 or to -- yeah. And to identify collagens better.

And another option of this polarization filter is the identification of some smaller particles, and I use this to look whether there are some particles. And if you're looking at the upper row in the right picture, you see that there are very, very small particles there, highlighted there. And it is usually just doing it without the filter, you will not see them because they are almost the same appearance as some cells. But when using the filter, you really see in a there is a foreign body.

On the left, you see a polymer fiber as I would have expected it, homogenously as a polymer. In the middle, you see that it is different. I have no explanation for this. The only explanation I can imagine is that there is some heterogeneity or change in the crystal structure that leads to this different

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rejection of the light there.

It is just a -- what I have seen there, I didn't know any literature making deeper studies to relate degradation to this, but I think it is a finding that may offer the option to make investigations using this filter when you want to look at the degradation of polypropylene.

Q. Do you have an opinion to a reasonable degree of scientific certainty that the image in the middle of the three-image set on page 72 is degradation?

A. As I tried to explain, there is no other information about the -- or confirmation that degradation can be seen by this but for my -- from my point of view, it is consistent with the opinion that there is some structural change, but I need further confirmation by further ongoing studies to prove this, but I just want to mention this.

Q. Okay. So just so I'm clear and I can stop asking questions about it, is it fair that you do not have an opinion to a reasonable degree of scientific certainty

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that the image in the middle of those three is degradation of the polypropylene mesh?

A. Yes.

Q. Okay. Is the image in the middle of the page of 72, is that your camera? What is that?

A. The middle here?

Q. Yes.

A. No, it's another image of this section where you see the different appearance of the polypropylene.

Q. I am sorry.

A. Down there is a polymer which seems to be intact as I would have expected it, and in the middle, you see some light changes of the appearance where I don't have any detailed explanation for the studies. It's a new finding.

Q. These samples came to you fixed in formalin, correct?

A. Yes.

Q. And slides were created.

Do you have any idea of the extent to which the creation of the slides

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could create any kinds of particles?
A. No. It's -- yes, of course, it has to be -- or the type of fixation, the type of handling can -- or can make some particles.
So, therefore, in the upper row, where you see on the left side some very small particles there, I cannot be sure whether this is done by the cutting, by the preparation of these sections for these stainings or whether it has been other reasons.
But if you're looking to the lower part of this, where you see a big particle, a fragment of the fiber, there you see that you already have some surrounding tissue response there and, therefore, it is clear that this particle has been implanted during the index operation there.
Q. Okay. Have you finished your comments and remarks about the top four images?
A. Yes.
Q. Moving now to the image that

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you just discussed, the single image at the bottom of page 72, and it says, "Around the separate particle, the usual tissue reaction can be seen is known from the tissue reaction to polymer fibers."
Do you have an opinion to a reasonable degree of scientific certainty that this was a particle in Mrs. Lewis that came out with her tissue explant?
MR. ANDERSON: Objection to form.
THE WITNESS: I've seen this in the sections which I got and saw this particle in these slides there.
QUESTIONS BY MR. THOMAS:
Q. Okay. Do you have an opinion as to whether this particle was -- strike that.
Do you have an opinion as to whether this image on page 72 is actually a part of the polymer that was cut?
MR. ANDERSON: Objection.
THE WITNESS: The polymer always is cut when you make this

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section, but in contrast to the particles on the -- in the upper row, you see that there is a reaction of cells around, which is very tied together to the surface of this particle and this needs time. So it is impossible that this particle is the result of the section and it shows clearly that even these particles have the typical foreign body reaction with the foreign body giant cells and the inflammatory infiltrate there.
QUESTIONS BY MR. THOMAS:
Q. What is your opinion with respect to the specific particle?
MR. ANDERSON: Other than what he just said?
MR. THOMAS: Right.
MR. ANDERSON: Okay. In addition to what you just said.
QUESTIONS BY MR. THOMAS:
Q. Any further comments that you have about this specific particle?
A. No.

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Q. Can you tell by looking at the -- what you've described as a particle on page 72 -- strike that.
Let's go to the next page. Wait a minute. Before we do that, the tissue reaction to the polymer on page 72, "Consists of an interzone of polymorphous mononuclear inflammatory cells with some confluent foreign body giant cells as a sign of chronic inflammation, mainly located at the interface the polymer."
Does that relate to the image above or the next page?
A. No, to this above.
Q. And that's what you were discussing before about showing the inflammation evidence that that's been going on for some time? Is that true?
A. This is the chronic foreign body reaction that is ongoing lifelong that happens to the filaments but to the particles as well and this is -- yeah.
Q. Page 73, the top of the page, you have two images, the commentary says,

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"The thickness of this inflammatory infiltrate is around 50 microns, but in some areas with close distance between the filaments, the entire space completely is filled out by this inflammatory infiltrate. In some areas, the accumulation of inflammatory cells indicates a more active, acute inflammatory reaction."

Tell me what it is about those slides that demonstrate that the entire space is filled out by this inflammatory infiltrate.

A. The fact that the entire space between the filaments is completely filled out by this infiltrate is not reflected in these two images.

Q. Okay. What is depicted in these images?

A. You see on the left, you see that I tried to measure the wall, the -- yeah, the inflammatory infiltrate, the thickness of the inflammatory infiltrate very close to the fiber and measured a distance of about 50 microns here.

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On the left side close to the polymer, you see some foreign body giant cells in the red -- in the right picture --

Q. Let's stop on the left for a second.

How many foreign body giant cells do you see?

A. I didn't count them.

Q. How do you determine what they are?

A. They are cells that -- that has confluent nucleus, more than one nucleus, and you have to go to the microscope and have to go through the depth to identify whether it's a giant cell, yes or not. Otherwise, it can be single cells laying over another.

Q. You've used the term "inflammatory infiltrate."

What is included in inflammatory infiltrate?

A. The inflammatory infiltrate, it can be best seen on the right side where you see a lot of these blue nucleus of these cells. These cells indicate this

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inflammatory infiltrate, and as we discussed yesterday, it is a wide field to identify which cells are specifically there. Usually there's about 40 percent that are positive for markers that represent macrophages. There are 30, 40 percent positive for markers that are related to lymphocytes as the main cells, but what's the name is specifically, we're still working on it.

Q. But the presence of the inflammatory infiltrate itself is normal; is that correct?

A. Normal as it is in principle, as it is compulsory of every foreign body reaction.

Q. What is abnormal about --

MR. ANDERSON: Hold on.

QUESTIONS BY MR. THOMAS:

Q. Did I interrupt you? I didn't mean to.

A. In quantity, in quality, that there is it, it is normal. If you mean is it normal in quantity, yeah. For heavy-weight, for a polypropylene, it is quantity that we

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can expect.

If you have other polymers, you won't expect so much.

Q. Okay. What is it about the nature of the inflammatory infiltrate that you see at the top of page 73 creates a risk of complications to Ms. Lewis?

A. The inflammatory infiltrate reflects an area of increased tissue remodelling. So you have an increased number of cell dying there in -- you have an increased turnover, you have an increased proliferation of these cells there because these inflammatory infiltrate has a more rapid turnover than a -- than other tissues.

Q. Is what you see --

A. And, sorry --

Q. I apologize.

A. And, therefore, the presence of an inflammatory infiltrate, that means that there is a chronic wound, means an intensified cell turnover with possible late risks, but -- and an increased risk for migration of the implant.

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QUESTIONS BY MR. THOMAS:
Q. There was no evidence in the Carolyn Lewis case that there was a migration of the implant, was there?
MR. ANDERSON: Objection.
THE WITNESS: I cannot state this from these sections.
QUESTIONS BY MR. THOMAS:
Q. Okay.
A. It's impossible.
Q. Can you state that from your review of the medical records in the case?
Do you know that?
A. Whether it was a real migration?
Q. Yes.
A. Of this? No.
Q. Okay. Are the findings that you've described in response to my questions concerning the images at the top of page 23 consistent with the reaction that any polypropylene mesh would have?
A. With any heavy-weight, small pore polypropylene meshes, they're completely

Page 595

consistent.
Q. Okay. Middle of page 73, what do we see?
A. We see, again, the holes where the polymers has been. You see an inflammatory infiltrate around it and it is -- it is an area where a folding and doubling of the layers can be seen, but not in this image, unfortunately, because we are limited with -- the lowest magnification is 40, and, therefore, it is impossible to get a good overview. To really -- either -- no, except of looking at the slides with a microscope where you can see that the configuration of the meshes are not in a plane area any longer, the alternative would be to make five, six images and to place them together.
As we made it, we have seen it already in some of the old documents where we made these long combination of various pictures to see the configuration of the meshes.
MR. ANDERSON: You said plane,

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you mean plane?
THE WITNESS: A plane, yeah.
QUESTIONS BY MR. THOMAS:
Q. So is it fair to understand that it's your opinion that your microscopic review of these slides shows you that there was folding demonstrated, but this slide that's in the middle, this image that's in the middle of page 73 does not show that?
A. That is -- that is correct.
Q. And you need to see the entire field in order to understand what you believe to be folding demonstrated by that slide?
A. That is correct.
Q. Is the rest of the action -- excuse me.
Is the rest of the reaction in the middle of page 73 that you've described consistent with the foreign body reaction to every heavy-weight, small pore mesh?
A. Yes.
Q. It is?
A. Yes.
Q. Thank you.

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MR. ANDERSON: He was waiting to make sure you distinguish heavy-weight, small pore. That's why he was smiling.
QUESTIONS BY MR. THOMAS:
Q. Page 73, the lower image, what does the lower image depict?
A. This is an image, I believe, that the -- the expression of folding is related to the lower image there. There you have the magnification of 40 and there you have a wider view of the meshes. And but in reality when you look to the section, you see further on where the mesh is going to. Here you have -- you see several places where the polymer has been -- this is hardly to believe that this is the mesh with the -- in plane area without doubling or folding that you get this section here.
Q. And help me, I am sorry, it's either late in the day or I'm not very smart, maybe both. The white areas in those, are those actual polymers?
A. These are some of the few parts

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where the polymers are still in place. The others you only see the holes, but, of course, there has been some polymers now laying in between or being removed by the knife.

Q. So in order for you to conclude that there's been folding here, you count both the polymers that you see and the holes where you suggest that polymers have been and conclude from that that there had to be folding?

A. Yes.

Q. Anything more than that that supports your contention that there's folding?

A. No. It is the appearance of the holes where the polymers has been and the geometrical configuration of these in a section.

Q. Is there anything else remarkable about the lower slide on page 73 other than your testimony about the folding?

A. No.

Q. Is the foreign body reaction

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depicted in the lower slide on page 73 consistent with heavy-weight, small pore meshes?

A. Yes.

Q. On page 73 at the top, what do we see?

A. This is an S100 staining and in the little of the left part of the image, there I expect there has been a polymer. It was removed by the preparation, and you have some areas with a brown staining there and this is consistent with the presence of a nerve in the area.

As we have three sections which are very close to each other, if you're looking to all three sections with S100, you see that it's not an artifact -- an artificial staining in one slide, but it is an ongoing structure going through all of these three slides so that I have no doubts that there's a small nerve.

Q. Okay. And as we said before, the mere presence of a nerve is not remarkable by itself?

Page 600

A. Not for me, but there are people who are -- for whom this is an important message.

Q. In the slides that you analyzed for Ms. Lewis, did you find any evidence of a neuroma?

A. No.

Q. Did you find any evidence of infection?

A. If I remember correctly, there was an area where you have an enhanced or where you have an intensified inflammatory infiltrate in this field. I know from Professor Klosterhalfen that the definition of infection sometimes is only the appearance of some more inflammatory cells than usually so, therefore, I cannot state it for sure that there has been one.

Q. Do you have an opinion to a reasonable degree of scientific certainty based on your review of the slides that's been provided to you that Ms. Lewis has an infection because of her mesh?

A. I don't have sure proof that

Page 601

there was an infection.

Q. So is it fair to understand you don't have such an opinion?

A. Have an opinion that I did not see it.

Q. Great.

MR. THOMAS: Can we take a break, please?

(Off the record at 3:54 p.m.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, I want to direct your attention to the chart that appears at the end of your report where you compile your findings from the -- your review of the slides and the spreadsheet has columns O, P, Q, R where you record what you found from your review of the slides.

Is that correct?

A. That is correct.

Q. The first column P says bridging, 1, less than 5 percent; 2, 5 to 30 percent; 3, 30 to 80 percent; and 4, greater than 80 percent.

How did you measure that?

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A. If you look to the entire section, you have some areas where you can identify something like a pore because you see some filament on the one side and on the other side. And if you look to the space in between two adjacent filaments, then you can assume this to be a pore. And if this is filled, if the area between the two neighboring filaments, if this is filled by fat tissue, I notice this in this chart and I only saw one or two times in all these sections that I got the image where I saw two filaments and the space in between was not filled by scar tissue.

So if I code this with more than 80 percent, then you got in all these sections four.

Q. Is 80 percent consistent with what you've described as scar plate formation?

A. Scar plate formation has been a term in a specific period of time. I think it's consistent.

Q. Okay. Well, do you use a

Page 603

different term now to describe what you find when you find bridging at greater than 80 percent?

A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have to be very precise in the definition of what you're thinking of.

Overall, this is completely in accordance what we expect that we have predominantly bridged or this -- these pores filled by scar tissue, yeah.

MR. ANDERSON: So the first one was macroscopically and then you said microscopically.

THE WITNESS: Microscopically.

QUESTIONS BY MR. THOMAS:

Q. So when you say 80 percent filled with scar, does that mean that there is not room for capillary vessels?

A. No. You have capillary vessels

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in scar tissue as well. So it means that you have scar and scar is mainly consistent with collagen leading to wound -- or being major -- majorly important for the wound contraction and some fibroblasts there and, of course, vessels. The only area where you hardly have vessels is very, very close to the polymer fiber.

But the appearance of vessels is no indicator of scar plate or scar net or --

Q. Do you know whether this scaling that you've done for the bridging is a method that's generally accepted by pathologists to look at mesh explants?

A. I made this scaling just for these cases to give -- to be able to give an impression of what I've seen there.

Q. What is the significance in your judgment of scaling of less than 5 percent? Excuse me, strike that.

What is -- what is the significance in your judgment of bridging less than 5 percent?

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A. You have to understand what we tried in these 15, 20 years is not only to make a qualitative description of the tissue reaction but to find some quantitative an -- or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make -- we introduced -- there has been some time when we use image analyzing. Now we're coming back to this coding, and the coding less than 5 percent means usually that you never see a bridging in this specimen.

Q. Why do you use 5 to 10 percent as your next range?

A. It is for scientific reasons you should have at least four different scoring levels, otherwise, you very likely go to the middle and then you will not see any difference so you need at least four different levels and you have to start from the extremes always and none and then you have to fill in between. I have no problem to make it different. And I made this coding before looking to the images, and, therefore,

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I was bound to this.
Q. Have you ever used this type of coding before in analyzing mesh explants?
A. We used such a type of coding very, very often to give a semi-quantitative analysis of our staining, yeah.
Q. When you say "we," who do you mean?
A. I, in my projects where we analyze these tissue samples, that is a major aspect before we starting the analysis to define the parameters and to define the coding, how to make the readout there.
Q. Okay. Do you always use the same numbers?
A. No. It varies from the specific question there, but it is about four to five.
Q. Okay. Under folding or shrinkage, that's "or," so if it's either folding or shrinkage, you capture it, correct?
A. Yes.
Q. Didn't we decide that every

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mesh is going to fold -- excuse me, didn't we decide that every mesh is going to shrink approximately 20 percent?
A. What I have been thinking of when looking for this folding was a double-layer structure which I cannot explain by the video I saw where the sling is implanted in a plane area, but when you have the impression that you have two or three layers of mesh materials on top of each other, I would say that there's a folding.
And shrinkage is if you have a configuration as a -- with a folding there in this area.
Q. So this says "folding or shrinkage."
A. Yeah.
Q. If you found shrinkage of 20 percent, would that be a positive finding?
A. This is a description of what can be seen there. What is the appearance of --
Q. I understand that.
What I'm trying to understand

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if you identified shrinkage of 20 percent, would that be a positive finding in your chart?
A. I didn't measure the degree of shrinkage. It was not possible to do so. It was just a configuration of the mesh.
Q. So if you saw any shrinkage at all, it would be a positive finding?
A. If I had the impression that the configuration of the mesh changes by pushing together, going to waves or by doubling, these are the two different things that indicates either shrinkage, pushing it together, or folding --
Q. The only reason I'm asking, Doctor, is because I thought we decided that all wounds shrink to some extent, generally at least 20 percent.
And so as I understood your testimony earlier, that means that every mesh explanted would be a positive finding here.
A. Sorry, it may be my fault that I call it shrinkage. I should have named it waving form or deformation of the shape due

Page 609

to shrinkage.
Q. Okay. The last category, "Nerve contact within one millimeter of sling."
Have we -- do we agree that there's nothing remarkable about nerve contact in itself? The nerves are going to be --
A. The fact that there are nerves in this place is not remarkable. The fact that these nerves are laying in this scar tissue gives a good explanation why some patients have chronic pain.
Q. Okay. And if PVDF mesh is placed for the treatment of stress urinary incontinence and comes in contact with a nerve, you would have the same risk of chronic pain, correct?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I would assume that if the nerve is laying in the fields of scar that is close to PVDF slings that there will be the chance

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for chronic pain as well.
However, the overall chance to get entrapped into scar tissue, I would expect is much lower and, therefore, the risk for pain is much lower when using large pore PVDF structures.
QUESTIONS BY MR. THOMAS:
Q. But we don't know that until we study it, correct?
A. We note from all our experience, from all our work that the risk for chronic pain decreases by using large pore structures and decreasing the amount of inflammatory reaction, yes, we know it already.
Q. From animal studies?
A. No. From clinical studies as well. We can go back to the guidelines where it is favored, the advantage of large pore meshes because of less chronic pain.
Q. Have we covered all of your opinions with respect to Carolyn Lewis?
MR. ANDERSON: Objection.

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THE WITNESS: I have the impression that we covered a lot. There are --
QUESTIONS BY MR. THOMAS:
Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did.
Have we covered it all?
MR. ANDERSON: Objection. With "whether you've covered it all."
MR. THOMAS: Well, I'm trying to go to his report, Ben, and I think I've covered every sentence in the report that deals with the mesh. If there's something that's in the report that I don't know about --
MR. ANDERSON: The only issue, Dave, is that he said that a lot of the slides that you can't put those types of fields into a one-dimensional report, and I told you that I would provide you mine and you were going to send me your guy's. So whether or not there are similar but expanded opinions based upon a larger review of

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a slide, that's the only thing I can think of. If that makes sense.
MR. THOMAS: I just want to make sure I haven't missed something in his report in the information that you provided to me here that I need to explore.
MR. ANDERSON: Anything significant.
MR. THOMAS: Either you or the doctor can tell me, if there's something else I need to explore, I want to do it, otherwise, I'm about to quit.
MR. ANDERSON: I think he's listed in his report in the grid and I think you've covered most all of that for her and I don't know if you covered all of the path slides that are in the back or not.
MR. THOMAS: Well, that's the problem is I don't know which ones are hers.
MR. ANDERSON: Yeah, you do.

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The grid says 13-23 and then the images correspond. That's one of the reasons I gave that to you to try to make that a little easier.
MR. THOMAS: Thank you.
Are they in order?
MR. ANDERSON: They're in order. Yours is in order of this grid, but hers should be last.
MR. THOMAS: They're not. No.
MR. ANDERSON: They're grouped together.
MR. THOMAS: Okay.
MR. ANDERSON: There we go. If you find the dark ones, it makes it easier.
MR. THOMAS: The first one that I have here appears to be -- and they're not numbered so I can't give you a page number, but in Exhibit 11, the first one that I have appears to match the one on page 71.
MR. ANDERSON: And that's why we said we have to go through them and

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see if they're -- all of them are listed. We just have to count them. There's 13 images in the back that I count of the report and you're in the middle of them right now.

MR. THOMAS: Let's go to the last one.

MR. ANDERSON: Show me which slide.

QUESTIONS BY MR. THOMAS:

Q. The last slide that I have in front of me, I'm sorry, it's not numbered, but it's BAL 13-23, which is the patient identifier. On the right, it has a scale of 100 microns, and in the middle of the slide, it shows what appears to be a measurement of 43.15 microns.

Is that a -- that's the one on page 73?

A. Uh-huh.

Q. Is that right?

A. Seems to. Yeah, I will agree.

MR. THOMAS: So you counted 13?

MR. ANDERSON: I think that's

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right.

MR. THOMAS: And there are 13 in the report.

(Klinge Exhibit 25 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Let me mark as Deposition Exhibit Number 25 the chart that we've been consulting, correct?

A. Yes.

Q. And that's where you recorded your findings from your review of the slides that we've been discussing, correct?

A. Yes, these are my results.

Q. And it also includes the information that Mr. Anderson provided about the chain of custody and the source of documents that you received, fair?

A. Yes.

Q. Dr. Klinge, did you ever tell Ethicon that they should not sell the Prolene® mesh used for the treatment of stress urinary incontinence?

A. No.

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MR. THOMAS: Those are all of the questions I have.

CROSS EXAMINATION

QUESTIONS BY MR. ANDERSON:

Q. Dr. Klinge, you were asked a few questions a few minutes ago by counsel regarding whether or not you had a residency or a fellowship in pathology.

Do you remember those questions?

A. Yes.

Q. Dr. Klinge, approximately when did you begin reviewing pathology slides of explanted meshes?

A. We -- I started to have a look through the microscope to these explanted meshes in 1994.

Q. And was that as part of the work with the IZKF-BIOMAT cross-functional team at Aachen University?

A. It was in relation to this project with the IZKF in collaboration with Professor Klosterhalfen at that time.

Q. Is it fair to say that

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Dr. Klosterhalfen trained you as a pathologist to review the histopathological slides of foreign body reaction to implanted meshes?

MR. THOMAS: Object to the form of the question.

THE WITNESS: Yes.

QUESTIONS BY MR. ANDERSON:

Q. You said "yes"?

A. Yes.

Q. Since that time in 1994 when you first began looking at slides from either animals or human tissue of explanted meshes, approximately how many times have you reviewed such slides and analyzed them? How many slides?

A. How many slides? It's difficult to estimate, but I've -- I estimate it's more than 25,000.

Q. And as part of your review of over 25,000 slides of the histopathology of explanted meshes, have you also published on some of those reviews?

MR. THOMAS: Object to the form

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of the question.
QUESTIONS BY MR. ANDERSON:
Q. In the peer-reviewed literature?
A. Yes. Yes.
Q. And have there been times where you have published in the peer-reviewed literature where you were the only pathologist that was reviewing the slides for the work that was contained in the study?
A. Yes.
MR. THOMAS: Object to the form of the question.
QUESTIONS BY MR. ANDERSON:
Q. You said "yes"?
A. Yes.
Q. Okay. And have you presented at Congresses and conferences to your colleagues and others with regard to your analysis of histopathological review of slides from explanted tissue in either humans or animals?
MR. THOMAS: Object to the form of the question.

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THE WITNESS: Yes. And it is a common procedure that a scientist made his own personal analysis of the tissues and made the analysis and the presentation of these data by himself.
QUESTIONS BY MR. ANDERSON:
Q. A little while ago counsel was asking you some questions about your choice of using the S100 staining with regard to your review of these 22 explants.
Do you recall that part?
A. Yes.
Q. He also asked you some questions to which you responded that this was something that you and Bernd Klosterhalfen had discussed many years ago about the choice of S100.
Do you remember that part of your question?
A. Yes.
Q. When you were answering these questions, you were talking -- strike that.
You never talked to Dr. Klosterhalfen about whether to use S100 for this case; is that correct?
A. Yes, that's correct, I never talked to him.
Q. Yesterday counsel was asking you some questions about this time period from 1994 to 2000 when you were in this cross-functional team with the IZKF-BIOMAT in Aachen with the group Ethicon Norderstedt.
Do you recall that part of your testimony?
A. Yes.
Q. He asked you whether that time period dealt with the treatment of stress urinary incontinence.
So my question is this: Dr. Klinge, do you consider that your work that you did in the '90s in developing VYPRO and in working with this BIOMAT team, the publications that you've done over the last 20 years, the conferences you've spoken at and all of the work that you've done in this field of biomaterial research and the tissue response to surgical meshes as well as your work as a hernia surgeon relates equally to

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hernia surgery mesh and the body's reaction to it, pelvic organ prolapse mesh and the body's reaction to it and sling mesh and the body's reaction to it?
MR. THOMAS: Object to the form of the question.
THE WITNESS: In regard to the biological response to these meshes, to these hernia meshes, there are a lot of similarities that allows us to make conclusions for both of this. There are, of course, severe differences or significant differences in regard to functional analysis or biomechanics, but the tissue reaction to a polymer is a lot of similarities.
QUESTIONS BY MR. ANDERSON:
Q. Is one of the similarities that all of this work that we've been discussing for the last two days and the things that I listed in my former question to you help scientists like yourself try to predict the tissue response to particular surgical meshes?

MR. THOMAS: Object to the form of the question.

THE WITNESS: Yes, in fact, it is this knowledge that we acquired in these years that allow us to make this analysis, to define requirements for textiles in this field and it is usually very appreciated when we present our experiences of these 15 years to urogynecologists.

QUESTIONS BY MR. ANDERSON:

Q. Thank you, Doctor.

Yesterday counsel asked you some questions as well regarding whether or not anyone in Aachen had a direct role in the development of ULTRAPRO™.

Do you recall those questions?

A. Yes.

Q. Whether or not anyone had a direct role in the research and development of ULTRAPRO™, do you consider the work that you and your team in conjunction with Ethicon did on VYPRO to be the foundational principles upon which ULTRAPRO™ was designed?

A. I think it was quite clear that ULTRAPRO™ was the successor of the VYPRO, and it just replaced an oligofilament mesh materials by monofilament and what we tried with the IZKF funding where we tried to do and realized with the PVDF that was done by Ethicon with polypropylene and Monocryl. And as a consequence, I guess that, therefore, I got royalties for the ULTRAPRO™, not only for the VYPRO because of this close relationship.

Q. So is it fair to say that you were receiving royalties for ULTRAPRO™ sales at the same time that you were telling Ethicon that you believed and that the Aachen group believed that PVDF was a superior material to polypropylene?

MR. THOMAS: Object to the form of the question.

THE WITNESS: There is an overlapping time period there.

So, again, just to make it clear, ULTRAPRO™ took over the principles of the VYPRO, the large pore concept, the material reduced

concept, therefore, it includes what we have collaborated for the VYPRO, but the specific details of the textile construction, there we haven't been involved.

QUESTIONS BY MR. ANDERSON:

Q. Okay. Yesterday counsel asked you some questions about Exhibit 9, which were the meeting minutes from the Suvretta meeting in 2003 in St. Moritz.

Do you remember that?

A. Yes.

Q. And he asked you some questions about the part of your presentation where you were discussing whether a scar plate or a scar net might begin to -- that would appear to be between 600 and 800 microns.

Do you remember that part of your testimony yesterday?

A. Yes.

Q. I want to show you what we've marked as Klinge Deposition Number 26 to your deposition.

(Klinge Exhibit 26 marked for

identification.)

QUESTIONS BY MR. ANDERSON:

Q. Do you recognize this publication?

A. Yes.

Q. And this is a publication in 2002 in the Journal of Surgical Research?

A. Yes.

Q. And are you one of the authors along with those from the BIOMAT -- the IZKF-BIOMAT group?

A. Yes, I was the author.

Q. And if you turn to the very last page under the "Acknowledgements" section as well as at the bottom of the page, does this indicate who provided funding?

A. Yes.

Q. And which company provided funding to this research?

A. Most supported by Ethicon and by the IZKF-BIOMAT.

Q. Because this was the time -- this is the time that you're working closely with them on developing VYPRO?

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A. No, this was after this time where we developed the VYPRO, but it was the time where we worked close together and had several ongoing projects together.

Q. And if we turn to page 213 of this article from 2002, if we look to the left-hand column, down where the words begin "As a result," what does that say?

Does it say, "As a result, the large pore sized greater than 2-millimeter mesh is integrated in a loose network of perifilimentary granulomas and plenty of fat tissue in between. Whereas the monofilament mesh with its smaller pores almost exclusively is imbedded into granulomas and scar tissue which bridges the whole pore diameter of less than 1 millimeter"?

Did I read that correctly?

A. Yes.

Q. Does that language that you've seen appear in Ethicon documents?

A. Yes.

MR. THOMAS: Object to the form of the question.

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THE WITNESS: Yes, I've seen it in many documents, and I'm sure I have repeated many of these phrases yesterday and today. Because it's still our belief.

QUESTIONS BY MR. ANDERSON:

Q. And given that -- strike that.

So this journal article that was published in -- based upon studies that were funded, at least in part by Ethicon, was in 2002, and your presentation in St. Moritz was in 2003.

So my question is you've listed a limit of 1,000 microns in the 2002 article with regard to a limit where fibrotic bridging may be seen, whereas in the panel discussion in Suvretta in 2003, you listed 600 to 800 microns.

Can you please explain that?

A. At that time, we had -- we made several attempts to make measure the pore and the bridging and we started at that time with the Marlex mesh and before I saw somewhere in the documents that there is a PowerPoint

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presentation in 2000, 2001 showing the distribution of the pores based on the Marlex mesh and there we indicated that there may be a -- that in these specimen that we measured at that time there was a limit in between 600, 800 microns.

In the other article, we want to express that a -- wanted to say or to be on a -- in a range that -- where you can expect that you get pores without this bridging, there we find this is 1 millimeter and in between, I guess, there has been the experiment that later on has been published by Conze with IPOM where we again measured all of these distances.

So, yeah, we learned that it depends from the polymer that is affected by the animal model there, but, however, we wanted to give a range or to give a hint where the border lays and, therefore, we said 1 millimeter.

If you look to the documents later on, in the presence of tension, Klosterhalfen advised 3 millimeters in some

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meetings there, and so I've no disagreement to this. So you see that there was a evolution of these advises and you have to be carefully looking to the specific conditions in what condition this was expressed there.

Q. And during that time period in the late '90s and early 2000s, were most of the heavy-weight, small pore meshes somewhere in this 600 to 1,000-micron pore size?

MR. THOMAS: Object to the form of the question.

QUESTIONS BY MR. ANDERSON:

Q. In a linear measurement?

A. Yeah. We didn't realize that the Prolene® is around this 1 millimeter in this. And maybe that there will be an upcoming question whether this millimeter is enough or it's not enough. If we have known at that time that this may be a problem, we would have thought a little bit more precisely to find maybe another border, to find another border there.

Q. Whether the limit is at 950 microns and 1,050 microns, is it safe to

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say that in all of the explants of Prolene® old construction 6-mil mesh, whether it was in the explants that you looked at from animal studies back during your time working with Ethicon or in any of the explants that had been done both in the 1,000 hernia explants as well as the greater than 400 explants that have been looked at from the pelvic floor, have you consistently had an observation with regard to the way Prolene® old construction 6-mil mesh that's used in the TVT® slings reacts in the tissue in terms of its pore size?

MR. THOMAS: Object to the form of the question.

QUESTIONS BY MR. ANDERSON:

Q. Have you noticed any sort of pattern or consistency there?

MR. THOMAS: Same objection.

THE WITNESS: In all of these sample that we had a look to it, Prolene® behaves as a heavy-weight, small pore mesh regardless whatever figures are printed out. The

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morphology of the tissue examination, with the extent of the geometry of the scar formation makes it clear that the old Prolene® is a -- behaves like a small pore -- heavy-weight, small pore mesh.

QUESTIONS BY MR. ANDERSON:

Q. And a few minutes ago when counsel was asking you some questions about the pathology slides and he said -- when you're looking at these slides of TVT® meshes, he asked you is this a normal fibrotic response or a normal tissue response.

Do you remember those types of questions?

A. Yes.

Q. And you said -- your testimony was normal or what we usually see with regard to a heavy-weight, small pore mesh.

Do you remember that part of your testimony?

A. Yes, I remember that part.

Q. Is that what you're referring

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to now with regard to the fibrotic bridging you've seen with Prolene®?

MR. THOMAS: Object to the form of the question.

THE WITNESS: Again, it is clear that it is normal for a high risk -- with a mesh for high risk for fibrosis. For a high-risk mesh, this is a normal reaction.

QUESTIONS BY MR. ANDERSON:

Q. And do you believe that the Prolene old construction 6-mil mesh used in TVT® is a high-risk mesh with regard to heavy-weight, small pore mesh that leads to fibrotic bridging and complications in patients?

MR. THOMAS: Object to the form of the question.

THE WITNESS: It's a high risk in regard to the extent of inflammation, scarring, shrinkage, dimension or the amount of material.

QUESTIONS BY MR. ANDERSON:

Q. And do you hold that opinion to

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a reasonable degree of medical and scientific certainty?

A. Absolutely. I'm convinced of it and there's huge evidence for this.

(Klinge Exhibit 27 marked for identification.)

QUESTIONS BY MR. ANDERSON:

Q. I show you what I've marked as Klinge Exhibit Number 27.

Have you seen this article before entitled, "The Argument for Light-Weight Polypropylene Mesh in Hernia Repair" from Surgical Innovation in 2005?

Have you seen this before?

A. Yes, I've seen it before.

Q. And do you know these authors, William Cobb, Kent Kercher and Todd Heniford?

A. Yes, I know them.

Q. And is Todd Heniford the hernia surgeon that you mentioned with reference to the Suvretta conference in 2003?

A. Yeah, I met him there and at several conferences in Europe as well.

Q. And you understand after

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reviewing materials that I've sent you, that Dr. Heniford is an expert for Ethicon in this litigation?

A. Even more, he's an expert for the argument of light-weight polypropylene. Of the use of light-weight meshes.

Q. If we turn to Dr. Heniford's publication, on page 2, which on this publication is on page 64 at the top left of Exhibit 27, what is the weight listed for Prolene®?

A. Prolene® here, it's given 105-gram per square meters.

Q. And it's lighter or heavier than Marlex?

A. It is heavier.

Q. And if we turn over to page 67 of this article by Dr. Heniford and his colleagues, do you see the section "Degree of Shrinkage"?

A. Yes, I see it.

Q. And reading under there, "One concern with the long-term implantation of mesh is the amount of shrinkage or passive

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compression the material undergoes. All available meshes regardless of their composition, experience a 20 to 50 percent reduction in their initial size."

Did I read that correctly?

A. Yes.

Q. Was that the state of knowledge as of 2005 based upon your understanding and your work that meshes could shrink from 20 to 50 percent?

MR. THOMAS: Object to the form of the question.

THE WITNESS: Yes, I agree.

QUESTIONS BY MR. ANDERSON:

Q. Is that part of what you were testifying to earlier when answering Mr. Thomas's questions regarding amount of shrinkage that you can expect from polypropylene meshes in the human body?

A. It's in accordance to what I said.

Q. If you turn over to page 68, in this Heniford article, if you look down to the second -- the column on the right in the

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sentence in Dr. Heniford's article, it says, "In contrast, the small pore mesh was incorporated entirely in perifilimentary granulomas and scar tissue which bridged the whole pore diameter of less than 1 millimeter."

Did I read that correctly?

A. Yes.

Q. And we have the diagrams down below showing that, "A 4-millimeter pore size will not show the granulomas touching of a light-weight mesh, whereas a 0.8-millimeter pore size does have the granulomas touching of a heavy-weight mesh."

Do you see that?

A. Yes, I see that.

Q. So according to this article, would Dr. Heniford and his colleagues' opinions be consistent with your own with regard to the percentage of shrinkage of meshes in vivo as well as the limit of around 1,000 microns to prevent fibrotic bridging?

MR. THOMAS: Object to the form of the question.

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THE WITNESS: All of these statements by -- published or concluded in this manuscript confirms my opinions in regard to shrinkage and required pore size to prevent bridging.

QUESTIONS BY MR. ANDERSON:

Q. And if we look to the left under the paragraph that begins, "In a dog model," does that paragraph indicate that polypropylene meshes shrink 30 to 50 percent of their original size within two to six months after implantation.

Do you see that?

A. Yes, I see it.

Q. Is that consistent with the opinions that you've stated to counsel here today?

A. Yeah. It is -- it confirms that the extent of shrinkage is higher in heavy-weight -- when using heavy-weight materials and can be reduced by using material-reduced meshes.

Q. And these ideas of the amount

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of contraction that could be expected in vivo of polypropylene meshes, was this information that Ethicon was aware of as a result of your work with them going back to the '90s?

MR. THOMAS: Object to the form of the question.

THE WITNESS: Yes. And yeah.

MR. THOMAS: Can we take a real quick break?

MR. ANDERSON: Yeah.

MR. THOMAS: Just ten seconds.

(Off the record at 4:44 p.m.)

QUESTIONS BY MR. ANDERSON:

Q. I don't remember the exhibit that we had with Professor Klosterhalfen with this document the other day, but if we have the minutes from 2007.

I'm going to show you what we marked the other day as Klosterhalfen Exhibit 11, which are the minutes from the meeting in Norderstedt in 2007.

You've seen this document before?

A. Yes, I've seen it.

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Q. And at that meeting, if you turn to page 2, do you see a heading "Factors Related to Mesh Shrinkage"?

A. Yes.

Q. By a Ms. Spychaj?

A. Yes.

Q. S-p-y-c-h-a-j.

MR. THOMAS: Object to the form of the questions related to that document. Was he at that meeting? Was he shown being in attendance?

MR. ANDERSON: I don't know. It doesn't show him being there.

MR. THOMAS: That's what I thought. Just a continued objection to his comments because he wasn't there.

MR. ANDERSON: Sure. I don't think he has to be present at meetings to be able to look at the PowerPoints that were there.

QUESTIONS BY MR. ANDERSON:

Q. And this PowerPoint entitled "Factors Related to Mesh Shrinkage," you've

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seen this document before?

A. Yes, I've seen it.

Q. And if we turn over into the document where it says "pore size" from this presentation in -- at Ethicon February 23, 2007, does that page indicate on a slide by Kirsten Spychaj, "Small porous meshes less than 1 millimeter lead to fibrotic bridging and increase shrinkage"?

A. Yeah.

Q. "Large porous meshes allow for a better and faster tissue ingrowth and less shrinkage and contraction"?

A. That is a correct summary.

Q. And down below where it says, "less than 1 millimeter" in the three little circles, these are drawings that you've seen before?

A. Yes, I've seen it.

Q. And these little red dots, would those indicate the peri-filamentous granulomas that you were referring to earlier?

MR. THOMAS: Object to the form

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of the question.

THE WITNESS: Maybe it can be interpreted in this way.

QUESTIONS BY MR. ANDERSON:

Q. So this would be a depiction of the size of pores after implanted in the body as a depiction of that, correct?

MR. THOMAS: Object to the form of the question.

THE WITNESS: That is correct. It's quite similar to the images that have been in the publication from Heniford.

QUESTIONS BY MR. ANDERSON:

Q. And have you seen this image of pores less than 1 millimeter leading to fibrotic bridging that we see here on -- I'll have to mark this as Plaintiff's Exhibit 28.

(Klinge Exhibit 28 marked for identification.)

QUESTIONS BY MR. ANDERSON:

Q. Is this an image that you've seen many times throughout the Ethicon documents that you've reviewed over the last

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two years in these litigations?
A. Yes, many times. Many times. And I've never seen any document showing that this is not a fact.
Q. Have you seen in any of the peer-reviewed literature in the last 20 years anyone who has disputed the fact that you need greater than 1 millimeter pore size to prevent fibrotic bridging in the tissues?
MR. THOMAS: Object to the form of the question.
THE WITNESS: No, I don't know. No, any study, any discussion that claimed to have facts that are in contradiction to this finding, to this estimate, to this interpretation.
QUESTIONS BY MR. ANDERSON:
Q. In the worldwide peer-reviewed literature over the last 20 years, have you seen any scientist or surgeon who has published regarding looking at -- has published regarding studies either looking at animal explanted mesh or human explanted mesh who have indicated that light-weight, large

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pore meshes versus heavy-weight, small pore meshes, that the heavy-weight, small pore meshes induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years refuted those findings based upon the indications that I just gave you?
MR. THOMAS: Object to the form of the question.
THE WITNESS: Do less. Larger pores do less fibrotic reaction, but I never saw or were confronted with someone disputing this findings.
QUESTIONS BY MR. ANDERSON:
Q. Have you ever seen in the peer-reviewed worldwide publication in the last 20 years any researchers other than yourself and Dr. Klosterhalfen who have reviewed as many explanted meshes from both animals and human beings for hernia, POP and SUI and reported on those in the worldwide literature, any other scientists other than the two of you?
MR. THOMAS: Object to the form

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of the question.
THE WITNESS: No.
(Klinge Exhibit 29 marked for identification.)
QUESTIONS BY MR. ANDERSON:
Q. Showing you what we will mark as Klinge Exhibit 29.
Showing you what we have marked as Plaintiff's -- I am sorry, as Klinge Exhibit 29, have you seen this -- have you seen this e-mail before during this litigation?
A. No.
Q. Okay. An e-mail from Joerg Holste to Jonathan Meek dated April 22, 2009.
Do you see that?
A. Yes, I see it.
Q. And in the first line, "Jonathan, the border for scar plate formation in small pore standard weight meshes was set around 1,000 microns."
Do you see that?
A. Yes, I see it.
Q. And is this Joerg Holste that

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you have worked with since the '90s going back all the way back to your IZKF-BIOMAT work with Ethicon to develop VYPRO?
A. That's true.
(Klinge Exhibit 30 marked for identification.)
QUESTIONS BY MR. THOMAS:
Q. Showing what we will mark as Klinge Exhibit 30.
This is a Klinge -- sorry, this is a clinical expert report from Piet Hinoul, medical director, Ethicon, department of medical affairs.
Do you see that?
A. Yes, I see it.
Q. It's dated September 25, 2012?
A. Yes.
Q. If you turn over to the page four pages back, which ends in Bates number 5782, under Prolene®, what does he list as the maximum pore size in millimeters?
A. The pore size of less than 1 millimeter.
Q. Thank you.

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Showing you what we will mark as Klinge Exhibit 31 -- wait a minute. Actually you -- strike that.

Showing you what was previously marked by counsel as Klinge Exhibit 21. There was this International Urogynecology Journal from Moalli and some of her colleagues entitled "Tensile Properties of Five Commonly Used Midurethral Slings Relative to the TVT®" from May 2008.

Do you remember counsel showing you this?

A. Yes, I remember.

Q. And he showed you on the top of what is page 57 of this article, he showed you the pore size of Gynecare being listed as 1379.

Do you see that?

A. Yes, I see it.

Q. And at the top of that under Table 1, it says, "Textile Properties Provided by the Manufacturers."

Do you see that?

A. Yes, I see it.

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Q. Did you see there -- strike that.

There was some questions by counsel about their measurements of the pore size in this article.

Do you see anywhere in this article where these authors measured these pore sizes?

A. No. As it is indicated there, they took it from the manufacturer.

(Klinge Exhibit 31 marked for identification.)

QUESTIONS BY MR. ANDERSON:

Q. Showing you what we will mark as Klinge Exhibit 31, under "Proprietary Mesh," do you see here where they list there under "Proprietary Mesh," it says, "Largest pore size"?

Do you see that?

A. Yes, I see it.

Q. And do you see 1379 -- 1,379 microns listed here by the manufacturer?

A. Yes, I see it.

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Q. Other than being listed in this -- I am sorry, let's go to the cover page.

It has, "Demand the most proven technology when selecting a midurethral sling. Make data and safety your choice" with the surgeon on the front.

Do you see that?

A. Yes, I see it.

Q. And in this document where they list 1,379 microns --

A. Yes.

Q. -- based upon your review of the depositions and the testing and the porosity and pore size evaluations by numerous Ethicon employees, have you ever seen any indication in any of those that there was a measurement of a pore size of Prolene® of 1,379 microns for the mesh used in TVT® anywhere in your review?

MR. THOMAS: Object to the form of the question.

QUESTIONS BY MR. ANDERSON:

Q. Other than on this promotional

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document by Ethicon, based upon your review of the depositions of Dan Burkley and all of the other documents that you've seen, have you ever seen them come up with a number of 1,379?

A. No, I didn't see it.

Q. In fact, according to their medical affairs director, Piet Hinoul, in this 2012 expert report, which was Klinge Exhibit 30, he says it's less than 1 millimeter, correct?

A. Yes.

MR. THOMAS: Object to the form of the question.

QUESTIONS BY MR. ANDERSON:

Q. Going back to this Moalli article -- turning to this page where it says Figure 4, is this uniaxial testing that's being shown?

A. Yes, it's uniaxial testing. It's quite similar to what we did with Professor Mühl's machine.

Q. And these are the photos of A, B and C that you have as images in your

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report, correct?
A. Yes.
Q. Okay. Doctor, I want to ask you one more thing about this Prolift+M® document.
Here it shows a weight of what would be 76 grams per centimeter squared.
Do you see that?
A. Yes, I see it.
Q. So this would be a lighter Prolene® mesh than actually the old construction 6-mil mesh, correct?
A. Per the other -- yes.
Q. So would you expect the pore size of the heavier weight Prolene® mesh to be just as small, if not smaller, than the Prolene® 76 grams per meter squared mesh?
MR. THOMAS: Object to the form of the question.
THE WITNESS: It is difficult to -- for me to find this relation between weight and pore size.
QUESTIONS BY MR. ANDERSON:
Q. And when you were looking at

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the pore size of Prolene® with Dr. Klosterhalfen back in the late '90s and early 2000s, was it your best estimate as of that time that the old construction 6-mil Prolene® fibers used in all of the TVT® devices had a pore size of 1,000 microns or less?
MR. THOMAS: Object to the form of the question.
THE WITNESS: It is when we made this linear measurements in one dimension, we got figures around 1 millimeter. When we made analysis by defining the area, we got figures around 1 millimeter. So it is Prolene® has pores in this area.
QUESTIONS BY MR. ANDERSON:
Q. Over time I think -- over time I think you were telling counsel that rather than using a linear dimension that the pore diameter dimensions and the distribution of the pore area of 1 millimeter in diameter became more important to you than the linear measurement.

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Do you remember that part of your testimony?
A. Yes. Yes.
Q. Okay. Do you consider the Mühl testing to be instructive to your opinions as to whether or not the Prolene® old construction 6-mil mesh used in all of the TVT® devices has pores that are -- any pores that are 1 millimeter in diameter?
MR. THOMAS: Object to the form of the question.
THE WITNESS: There are some pores around 1 millimeter.
QUESTIONS BY MR. ANDERSON:
Q. And would a Prolene® mesh that has pores of pore area right around 1 millimeter be as safe as a pore size of ULTRAPRO™ or VYPRO with pores that are in the 3 to 5 millimeter range in diameter?
MR. THOMAS: Object to the form of the question.
THE WITNESS: No. It is very clear that large pore meshes with 3, 4 millimeters has very, very low risk,

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and it is clear that small pores mesh has higher risk. And biologically, this is true for Prolene® because it bridges all the time. If you look to the textile property -- the textile porosity, you see that the pores are around 1 millimeter. But if you look to the effective porosity, it is quite low. And, therefore, this is consistent.
(Klinge Exhibit 32 marked for identification.)
QUESTIONS BY MR. ANDERSON:
Q. Showing you what we will mark as Klinge Exhibit 32. It's a document that I have previously provided to you.
Do you recall that, Dr. Klinge?
A. Yes.
Q. And if you look at the front page of this PowerPoint, are these the same authors that we looked at in this Moalli, Abramowitch, Feola article that counsel showed you earlier today?
A. I agree.

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Q. And if you turn to the third page of this document, first of all, is the date, May 24, 2013?
A. Yes.
Q. And if you look down into the middle slide on that page under "Material Parameters, Textile and Structural Properties of Implant Materials," what does the sixth point say?
A. The sixth point means that --
Q. What does it say, number 6?
A. Effective porosity.
Q. And under "Biomechanics," does it list the Mühl article that you did with Professor Mühl in 2008?
A. Yes.
Q. From your reading of the Feola, Abramowitch and Moalli article, was this your understanding that this is a group out of Pittsburgh, Pennsylvania?
A. Yes.
(Klinge Exhibit 33 marked for identification.)

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QUESTIONS BY MR. ANDERSON:
Q. One last document. I'm going to show you Klinge Exhibit 33.
Showing you this document that we've marked as Klinge 33. Sorry.
Are you familiar with Christoph Walther?
A. Yes, I know him.
Q. Is this a name that you had mentioned yesterday as someone you had worked with from R&D in Hamburg at Ethicon facilities there?
A. Yes.
Q. And even going back to your work with Ethicon from the late '90s in the development of VYPRO?
A. Yes.
Q. And this is a letter from Christoph Walther to Quentin.
Are you familiar with a Quentin Manley?
A. No, I don't know.
Q. And this second paragraph here is talking about, "This applicant is a German company in Aachen, FEG Textiltechnik, and the inventors are U. Klinge and B. Klosterhalfen, RWTH Aachen, and two peoples from FEG."
Do you see that?
A. Yes, I see it.
Q. And then, "FEG has some products for hernia repair on the market and also for pelvic floor surgery."
Did I read that correctly?
A. That is correct.
Q. "In Germany, these products are distributed through Dahlhausen, a big dealer for medical device."
Do you see that?
A. That is correct.
Q. And then it talks about, "The technology is based on a special material, PVDF."
Do you see that?
A. Yes.
Q. And it says that, "Our material, Ethicon's material, Pronova is comparable to PVDF."
Do you see that?

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A. Yes, I see it.
Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago?
MR. THOMAS: Object to the form of the question.
THE WITNESS: Yes.
QUESTIONS BY MR. ANDERSON:
Q. And you've seen that patent, correct?
A. Yes, I've seen it.
Q. To your knowledge, has Ethicon ever acted upon that patent and tried to produce a surgical mesh with PVDF in it for the pelvic floor or for hernia?
A. I didn't ever get any positive information for this.
Q. And then if we look at the next paragraph down, "In extremely, this patent applications could be a strict restriction for Ethicon to sell implants manufactured from Pronova monofilaments. In my eyes, Pronova monofilaments are extremely good candidate as implant material, very high

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flexibility, low bending stiffness, Y-sterilization -- gamma -- without loss of tensile strength in contrast to polypropylene, long-term stability in human body."

Did I read that correctly?

A. Yes.

Q. And do you know that Christoph Walther is one of the top polymer scientists at Ethicon Norderstedt?

A. Yes.

MR. THOMAS: Object to the form of the question.

QUESTIONS BY MR. ANDERSON:

Q. Did Christoph Walther ever contact you to ask you about working with you on a PVDF mesh for Ethicon's catalog of products for either hernia repair, pelvic organ prolapse repair or stress urinary incontinence repair?

A. No, he didn't do.

Q. Counsel asked you whether or not you were aware of any clinical studies or randomized controlled trials that would look

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at the effect of particle loss of surgical meshes in the tissue.

Do you remember that part of your testimony?

A. Yes.

Q. Do you need a clinical study result, Dr. Klinge, in order to form your opinion that excess polypropylene particles in a human tissue can elicit a greater inflammatory response?

MR. THOMAS: Object to the form of the question.

THE WITNESS: No, there is -- as I tried to express earlier, there is a huge evidence that increase the material, the increase of surface of polymers leads to an increased and intensifying foreign body reaction and with all of the risks.

QUESTIONS BY MR. ANDERSON:

Q. Counsel asked you some questions earlier today regarding the in vivo forces that would be realized underneath a woman's urethra.

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Do you remember that?

A. Yes.

Q. He was asking you for articles that you may have or be aware of that relate to what the estimated forces underneath the bladder may be that the TVT® sling may be subjected to.

Do you remember that part of your testimony?

A. I remember it.

Q. Turning now to Klinge Exhibit 11, which was your expert report.

A. Uh-huh.

Q. I was going to ask you some things counsel did not.

Starting with page 18 of your report and going through page 23 of your report, in those five pages, did you go through an analysis of various literature as well as internal Ethicon documents regarding estimated forces that one could anticipate being on the TVT® sling underneath the bladder neck?

MR. THOMAS: Object to the form

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of the question.

THE WITNESS: Yes.

QUESTIONS BY MR. ANDERSON:

Q. Yes?

A. Yes.

Q. And when you gave counsel a measurement -- strike that.

When you listed to counsel that you could anticipate less than 10 newtons per centimeter in terms of a force that could be placed upon the sling under the bladder neck, is that reflected in the forces that you list on page 23 of your report?

A. Yes, that is a brief summary of all this knowledge collected on these pages.

Q. And after you collected the knowledge that's on these pages, did you then use these figures on page 23 of Klinge Exhibit 11 in order to instruct Professor Mühl as to the forces that you thought he should put on the machine to test the TVT® laser-cut and mechanical-cut meshes?

A. In fact, that was the reason to define the range for the measurements that we

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collected all of this data.
Q. Counsel also had a statement to you, "There are no in vivo studies regarding whether high effective porosity under stress will help improve biocompatibility." Taking that statement out of your 2007 publication with Professor Mühl, "The New Objective Measurements for Porosity."
Do you recall that part of your testimony today?
A. Yes.
Q. Is the concept of effective porosity to allow for proper tissue healing in between the pores?
MR. THOMAS: Object to the form of the question.
THE WITNESS: Yes.
QUESTIONS BY MR. ANDERSON:
Q. And is effective porosity an area that would allow for good tissue healing in pore sizes that are greater than 1 millimeter in all direction?
A. Yes.
Q. Based upon your work in this

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area for the last 20 years, your work in the '90s with BIOMAT and with Ethicon, the development of VYPRO, your publications, your Congresses, all of your work in this field for two decades, do you have an opinion to a reasonable degree of medical certainty as to whether or not the Mühl testing in looking at the 1 millimeter pore diameter of meshes will impact the biocompatibility of that mesh in the tissue?
MR. THOMAS: Object to the form of the question.
THE WITNESS: Yes. I have no doubts about that this is the effect.
QUESTIONS BY MR. ANDERSON:
Q. And do you believe that putting the machine at a 1,000-millimeter limit is based upon all of the work that you've done for the last 20 years, you, Klosterhalfen and the rest of those involved both in Aachen as well as Ethicon in this area of tissue reaction to surgical meshes?
MR. THOMAS: Object to the form of the question.

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THE WITNESS: It is based on the current data that are available, which is known to Ethicon as well.
MR. ANDERSON: That's all of the questions I have for right now, Dr. Klinge.
THE WITNESS: Thank you very much.
MR. ANDERSON: He's got a few.
REDIRECT EXAMINATION
QUESTIONS BY MR. THOMAS:
Q. Dr. Klinge, Exhibit 30, which was the expert report from Piet Hinoul, Mr. Anderson already showed you on page 4 of Exhibit 30 that the weight for the Prolene® mesh is lower than the weight that you typically recorded for the first generation old Prolene®, correct?
A. I tried to calculate there are -- there has been milligram per square centimeters. Usually, it's gram per square meters. I assumed that the usual data of 108-gram per square meter would be 10.8-milligram per square centimeters.

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Q. Do you know whether this is the old Prolene® mesh used in TVT® --
A. It shouldn't be the old one.
Q. It should be the 5-mil hernia repair mesh or some other one?
A. I don't know.
Q. It's -- this is the -- your best interpretation of Exhibit 30, page 4 for the entry of Prolene® is that this is not the first generation Prolene® mesh that you tested and that's used in the treatment of stress urinary incontinence, correct?
A. I just see the name Prolene®. I see this white, and this is inconsistent to what we have seen with other tables where there was Prolene® and -- so this is -- by the way, this is a report from Ethicon.
Q. I know.
A. And I would expect that they indicate clearly what they shared in their table there because this makes a lot of confusion in all the subsequent -- when someone else took over these data there.
Q. Doctor --

A. I just want to say it and have it --
Q. And you did.
A. -- documented.
Q. And you did.
But so I can say it and document it, this is not the first generation Prolene® mesh, correct?
A. It looks like, yes.
Q. It looks like it's not?
A. It looks like it's not.
MR. THOMAS: Thank you. That's all I have.
RECROSS EXAMINATION
QUESTIONS BY MR. ANDERSON:
Q. And even with a later generation Prolene® mesh, they still can't get their pore sizes or Ethicon still chooses not to get their pore sizes above 1 millimeter, correct?
MR. THOMAS: Object to the form of the question.
THE WITNESS: Whatever they presented there as a Prolene® there,

yes, I agree.
MR. ANDERSON: No further questions.
MR. THOMAS: Thank you, Doctor.
MR. ANDERSON: Thank you.
(Deposition concluded at 5:16 p.m.)

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CERTIFICATE

I, CARRIE A. CAMPBELL, Registered Professional Reporter, Certified Realtime Reporter and Certified Court Reporter, do hereby certify that prior to the commencement of the examination, Uwe Klinge was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

_____
CARRIE A. CAMPBELL,
NCRA Registered Professional Reporter
Certified Realtime Reporter
Missouri Certified Court Reporter #859
Illinois Certified Shorthand Reporter #084-004229
Notary Public
Dated: December 3, 2013

ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
Prof. Dr. Med. Uwe Klinge DATE

Subscribed and sworn to before me this _____ day of _____, 20 _____.
My commission expires: _____

Notary Public

ERRATA

PAGE	LINE	CHANGE/REASON

LAWYER'S NOTES

PAGE	LINE